COMPARISON OF REAL TIME ULTRASOUND ASSISTED VERSUS CONVENTIONAL LANDMARK TECHNIQUE FOR SPINAL ANAESTHESIA IN PATIENTS WITH DIFFICULT SPINE ANATOMY

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Submitted By

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DECLARATION BY THE CANDIDATE

I hereby declare that the thesis entitled "**COMPARISON OF REAL TIME ULTRASOUND ASSISTED VERSUS CONVENTIONAL LANDMARK TECHNIQUE FOR SPINAL ANAESTHESIA IN PATIENTS WITH DIFFICULT SPINE ANATOMY**" submitted towards partial fulfillment of the requirements for the award of **MD in Anaesthesiology** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr.Shikha Gupta**,Professor, Department of Anaesthesiology, **Dr. Kamakshi Garg**, Professor, Department of Anaesthesiology, **Dr.Tanveer Singh,** Associate Professor, Department of Anaesthesiology. No part of this thesis has formed the basis for the award of any degree previously.

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Dedicated

to

my Family

&

Teachers

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ABBREVIATIONS

ASA	American Society of Anesthesiologists
BMI	Body Mass Index
IQR	Inter quartile range
LFD	Ligamentum flavum dura mater
LM	Landmark
LS	Lumbar spine
PLL	Posterior longitudinal ligament
PSO	Parasagittal oblique
RUS	Real time ultrasound
SAB	Subarachnoid block
SD	Standard deviation
TI view	Transverse interlaminar/interspinous view
TM	Transverse median view
US	Ultrasound

ABSTRACT

Background and Aim: Spinal anaesthesia with conventional landmark technique can be challenging in patients with anatomical alterations of the lumber spine, such as scoliosis or previous lumbar spine surgery or poorly palpable spinous processes, We aimed to compare the efficacy of real time ultrasound guided paramedian technique (group B) with conventional landmark guided paramedian technique spinal anaesthesia (group A) in patients with difficult spine anatomy.

Materials & methods: Seventy patients belonging to ASA grade I-III, aged 18 years with difficult spine anatomy scheduled for elective surgeries under spinal anaesthesia, were included in this prospective randomized study. Patients were randomly allocated to either of 2 study groups of 35 patients each by computer generated randomization codes contained in sealed, sequentially numbered envelopes**.** The primary outcome of our study was to compare the first needle insertion attempts required for successful dural puncture between both the techniques. The secondary outcomes were comparing of total number of attempts (needle insertions plus needle redirections), the total procedure time (assessment time plus procedure time) required for successful dural puncture, peri procedural pain and discomfort scores and complications, if any between both the groups.

Results : The incidence of successful dural puncture on first attempt was significantly higher in group B (40.0%) as compared to group A (11.4%) (p value 0.006). The mean number of total attempts was lower in group B 2.23(±1.21) than in group A 3.43(±1.54), which was statistically significant with p value 0.001.The mean time taken to identify the anatomical landmarks in group B was higher [155.83 (±37.59)sec] than in group A [29.97(±9.72)sec] which was statistically significant with p value 0.001. The mean time taken for spinal anaesthesia in group A [1.42±0.46min] was significantly higher as compared to that in group B (0.67±0.21) min which was statistically significant with p value 0.001.

Conclusion: A real time ultrasound guided paramedian approach for spinal anaesthesia in obese patients significantly decreases the number of needle insertions and redirections leading to significantly decreased periprocedural discomfort.

Keywords: Conventional landmark, difficult spine, dural puncture, paramedian approach, real time ultrasound, spinal anaesthesia.

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INTRODUCTION

Spinal anaesthesia is a commonly performed procedure and is largely performed with a "blind" technique based on surface landmarks. In blind technique palpation of bony landmarks is done to identify the level and point of needle insertion.[1] Tuffier line (the horizontal line connecting the superior iliac crests) is used as a surface landmark in this technique.[2] While surface anatomical landmarks are helpful, they are nonetheless surrogate markers.[3] Landmark - based approaches do not consider all anatomical variations or abnormalities and often result in incorrect identification of a given lumbar intervertebral space.[3,4] In patients with indistinct or impalpable surface bony landmarks and positioning challenges such as lumbar scoliosis, osteoarthritis, kyphoscoliosis and previous spinal surgery, neuraxial blocks can be difficult to perform. The resultant multiple attempts to administer spinal anaesthesia in these individuals increases the risk of post dural puncture headache, trauma to neural structures, paraesthesia, higher incidence of spinal hematoma, epidural hematoma, radicular pain, patient discomfort and bloody tap in the spinal needle.[4-10]

According to the second American Society of Regional Anaesthesia Consensus on Neuraxial Anaesthesia and Anticoagulation, the ideal approach to provide spinal anaesthesia is via a single skin puncture with no needle redirection.[11]

Various modifications have been described to reduce the morbidity associated with attempts and repetitive needle passes.[12] These includes landmark guided paramedian approach, pre-procedural ultrasound guided paramedian approach, pre-procedural ultrasound guided midline approach, real time ultrasound guided approach.[12]

Neuraxial ultrasound is a relatively recent evolution in the area of regional anaesthesia. It allows anaesthesiologist to preview spinal anatomy, identify paramedian position and determine the intervertebral space for accurate needle placement. Ultrasound can be used as an alternative or an addition to manual palpation method to identify

intervertebral space in patients with difficult spinal anatomy. Ultrasonography of the lumbar spine reveals anatomical information that is not obtained by physical examination, including depth of the ligamentum flavum, width of the interspinous spaces, and spinal bone abnormalities, including scoliosis.[13]

Pre-procedural ultrasound of the spine facilitates central neuraxial blockage and is especially beneficial in patients whose surface landmarks are difficult to palpate or are distorted due to obesity, spinal abnormalities or previous spinal surgeries[14] as it defines the anatomy and makes it easier to determine the precise location and direction of a needle's insertion. Although pre-procedural ultrasound guided technique has shown higher success rates than landmark-based technique but it also has certain limitations.[13]

With pre-procedural ultrasound technique there is a potential for error in the process of having to “remember” the degree of cephalad to caudal and lateral to medial angulation required after pre-puncture skin marking. Also, skin distortion in elderly patients with mobile and loose skin might result in an inaccurate needle insertion point. Lastly, there is an inherent degree of inaccuracy when marking the needle insertion point on the skin during the pre-procedural scan.[5] A real time ultrasound guided approach might further improve on these limitations of ultrasound assisted pre-puncture technique by allowing real time monitoring of the needle's progress during puncture.[3]

There are limited studies which have compared the real time ultrasound guided paramedian approach for spinal anaesthesia with conventional paramedian landmark technique in patients with difficult spine anatomy.[15] So we proposed to conduct a study to investigate whether real time ultrasound guided paramedian technique of spinal anaesthesia offers any advantage over conventional landmark paramedian technique in patients with difficult spine anatomy.

We hypothesized that real time ultrasound scanning will facilitate subarachnoid block and improve first attempt success rate in patients with difficult spine anatomy.

AIMS AND OBJECTIVES

Primary Aim To compare the rate of successful dural puncture between ultrasound assisted paramedian technique versus landmark guided paramedian technique in patients with difficult spine.

Secondary Aim

- To compare the number of needle insertion attempts and needle redirections required for successful dural puncture in both groups.
- To compare the total procedure time.
- To compare peri-procedural pain, discomfort scores and complications if any.

REVIEW OF LITERATURE

The first planned spinal anaesthesia for surgery was administered by August Bier in 1898.[16] Spinal anaesthesia has been traditionally performed using a surface landmark based 'blind' technique. Landmark guided spinal anaesthesia can be performed using midline, paramedian and lumbosacral approaches.[17]

Current practice uses Tuffier's line (an imaginary line drawn between the iliac crests that theoretically intersects the body of L4) and palpation of spinous processes in order to perform the procedure. However, Tuffier's line is not a reliable marker of the appropriate spinal level in many patients.[15] Correct identification and cannulation of the subarachnoid space determine the success or failure of the technique. However, subarachnoid block can be difficult and challenging for the anaesthesiologist in cases where surface landmarks are absent, indistinct and distorted because of obesity, previous spinal surgery, deformity and degenerative changes of ageing.[5] In such cases multiple insertion attempts are associated with several complications like epidural hematoma, nerve damage, post dural puncture headache and infection.[6-10] This may lead to pain, discomfort, dissatisfaction and refusal by the patients to have spinal anaesthesia for any subsequent surgery.

Ultrasound is a portable and safe technology that is increasingly being used to facilitate anaesthesia procedures. Bogin and Stulin were first to use ultrasound for lumbar puncture in 1971.[18] Since then, ultrasound imaging has become a popular tool to perform neuraxial anaesthesia. Ultrasound can help in understanding a patient underlying anatomy, especially in those with anatomical abnormalities that would not otherwise be appreciated by surface landmarks.

Use of ultrasound can reduce the level of difficulty by giving the user a clear point for needle insertion and guidance to the angle, direction and depth of insertion. Pre-procedural ultrasound have shown to decrease the number of needle passes to achieve successful block to almost half,[13] as ultrasound is capable of identifying the precise location of an

interlaminar space through which a needle can be advanced.[19] Pre-procedural ultrasound guided spinal anaesthesia helps to reduce the number of multiple insertion attempts, hence more acceptable and less risky for the patient.[17] However, the actual needle insertion in the pre-procedural ultrasound assisted technique still remains a 'blind' procedure and the anaesthesiologist remains unaware during the actual needle insertion, and may still face difficulty in directing the needle through the interlaminar space.[20,21] This limitation of pre-procedural ultrasound can be overcome by using real time ultrasound. With the help of real time ultrasound, active needle tracking allows experienced providers to visualize their needle as it travels the tissue layers. Adjustment of needle trajectory, as well as potential confirmatory tip location, can be done with real time imaging. Furthermore, when a patient moves from their previously-scanned posture, real time scanning enables readjustment without the need for modification.[21]

Chong SE et al conducted a randomized controlled trial on 60 patients aged (18 to 75 years) with BMI <30 kg/m2 to compare the efficacy of real time ultrasound guided paramedian versus landmark guided paramedian spinal anaesthesia.[11] Successful dural puncture on single needle pass were higher in real time ultrasound group (47%) than in the landmark group (20%) and the mean time for a successful dural puncture was less in real time ultrasound group [0.69(1.01)minutes] than the landmark group [1.60(1.19) minutes]. They concluded that the real time ultrasound guided paramedian approach improves the success rate of dural puncture. It also reduces the number of attempts required, improves the success rate of a single needle pass, and shortens the time required for dural puncture.

Bhardwaj D et al performed a prospective randomized controlled study on 150 patients aged 20 - 65 years, having BMI <30kg/m2 with normal spine and scheduled for orthopedic surgeries.[22] They compared the feasibility and efficacy of real time ultrasound guided subarachnoid block with pre-procedural ultrasound assisted and landmark guided subarachnoid block using paramedian approach in

these patients. The number of needle attempts for successful dural puncture was less in Pre-procedural group (1.00 ± 0.28) as compared to landmark group(1.05 ± 0.35)and real time US-guided group(1.03 ± 0.26) with P value of 0.436 and was statistically non significant. However, the time taken for the completion of the successful SAB was more in real time US guided group as compared to landmark and pre - procedural groups .They concluded that the real time ultrasound guided spinal block provides visualisation of the needle trajectory in real time; however, the advantages in terms of needle attempts for successful SAB and time for the performance of the block are comparable to the pre-procedural ultrasound guided spinal block in patients with a normal spine.

Elsharkawy H et al did a randomized controlled clinical trial on 38 patients scheduled for total hip or knee arthroplasty to compare real time ultrasound guided paramedian versus landmark guided spinal anaesthesia in patients with difficult spine anatomy.[15] They concluded that in patients with difficult spine anatomy real time ultrasound guided group required more time(256 seconds) than in landmark group(117 seconds) but the number of needle insertion attempts were lower in real time ultrasound group(1.4±0.6) as compared to landmark group(1.6±1.1).

Raghu K C et al conducted a prospective randomized double-blind study on 50 subjects to compare the efficacy of real time ultrasound guided paramedian with pre-procedural ultrasound guided paramedian technique for identification of subarachnoid space in obese patients with BMI >30 kg/m^2.[4] The success rate of correct identification of the subarachnoid space on first attempt was 96% in real time ultrasound group. In their study the mean total number of attempts was significantly less in real time ultrasound group (3.90±0.51) as compared to pre-procedural ultrasound group (4.26±0.44) and the total time taken for successful lumbar puncture was less (27.90±5.30) in pre-procedural ultrasound group than in real time ultrasound group (44.80±9.28). They concluded that real time ultrasound is better than pre-procedural ultrasound for identification of spaces.

Ravi RP et al performed a randomised single blinded controlled study on 80 patients with BMI > 30kg/m2 who were scheduled for elective lower abdominal, perineal and lower limb surgeries under spinal anaesthesia.[23] They compared the efficacy of real time ultrasound guided paramedian approach and pre-procedural ultrasound guided paramedian approach in obese patients. They found that the number of successful dural puncture's during the first needle insertion was higher in real time ultrasound group (RUS 60%) as compared to pre procedural ultrasound group (PUS 27.5%) and was statistically significant. The success rate for achieving successful dural puncture in both groups were similar (RUS 98%, PUS 92.5%). The median number of attempts were more 4 (IQR 2-4) in pre-procedural ultrasound group than in real time ultrasound group 2 (IQR 1-2 with) P value < 0.001. They concluded that the time taken for the identification of the space, the number of attempts, number of passes, and the time taken for successful lumbar puncture was more in the pre procedural group as compared to the real time ultrasound group

LIU Yong et al did a non randomized study on 42 patients with BMI < 30kg/m2 who were planned for orthopaedic and obstetric procedures with real time ultrasound guided spinal anaesthesia using a paramedian transverse approach.[24] The main aim of this study was to assess the feasibility and efficacy of real time ultrasound using a paramedian transverse approach. The success rate for single skin puncture with one or more needle passes was 95.2%. The mean time taken for localization of the puncture point was 26.7±11.1 seconds and the median time taken from skin puncture to the end of local anaesthetic drug was 148 seconds. They successfully performed real-time ultrasound-guided spinal anaesthesia in these patients with this approach and concluded that to establish effectiveness and safety of this approach further studies comparing real time ultrasound with blind technique and other ultrasound guided technique are required.

Chin KJ et al conducted a prospective, randomized, controlled trial to investigate the impact of an ultrasound guided technique on the ease of performance of spinal anaesthesia in patients with difficult surface

anatomic landmarks.[5] Poor surface anatomic landmarks are highly predictive of technical difficulty in neuraxial blockade. They assessed 120 orthopaedic patients with one of the following inclusion criteria 1) BMI > 35 kg/m² and poorly palpable spinous process 2) Moderate to severe lumbar scoliosis; or 3) Previous lumbar spine surgery. Patients were randomized to receive spinal anaesthesia with the conventional surface landmark guided technique (group LM) and with a pre-procedural ultrasound guided technique. They showed that the pre procedural ultrasound guided technique improved the efficacy of spinal anaesthesia by reducing the technical difficulty of spinal anaesthesia. They found that successful dural puncture on the first needle insertion attempt was more in pre-procedural ultrasound group (65%) than in surface landmark group (32%). However, they reported that more time was required to establish landmarks in pre-procedural ultrasound guided group (6.7±3.1 minutes) as compared to palpation with surface landmark group (0.6±0.5 minutes). They concluded that pre-procedural ultrasound imaging facilitates the performance of spinal anaesthesia in the non obstetric population with difficult anatomical landmarks.

Park SK et al randomized 80 patients aged at least 60 years undergoing orthopaedic surgery to receive spinal anaesthesia by the paramedian approach by either conventional surface guided palpation (landmark group) or pre-procedural ultrasound assisted technique (ultrasound group).[25] They concluded that the ultrasound assisted paramedian spinal anaesthesia significantly reduces the number of needle manipulations required for success dural puncture, increases the success rate at first pass and decreases peri-procedural pain and patient discomfort compared to the landmark guided paramedian technique in the elderly.

Park SK et al performed a prospective, randomized, controlled study on 44 patients with abnormal spine anatomy and compared pre procedural ultrasound assisted paramedian technique with landmark guided paramedian technique.[26] They observed that the pre-procedural ultrasound guided group had a substantially greater first attempt success rate (65%) than the landmark guided group (17.5%).

They concluded that the pre-procedural use of ultrasound significantly reduced the technical difficulties of spinal anaesthesia in patients with abnormal spinal anatomy compared with the landmark guided technique.

Kampitak W et al conducted a prospective, randomized, controlled study on 70 patients comparing landmark and ultrasound guided technique in paramedian spinal anaesthesia in patients aged > 65 years undergoing total knee or hip arthroplasty.[17] They found that the use of pre-procedural ultrasound guidance in paramedian spinal anaesthesia in elderly patients resulted in a significant decrease in the number of needle redirection and insertion attempts as well as reduction in associated complications like traumatic puncture and paresthesia as compared to the conventional paramedian technique.[11] They preferred paramedian approach in elderly patients because of presence of degenerative changes in the structural elements of the spine, narrow interspinous and interlaminar spaces, ossification of ligaments, and hypertrophy of facet joints.

Rizk MS et al did a prospective, randomized, controlled study on 180 patients and compared pre-procedural ultrasound guided midline approach, pre-procedural ultrasound guided paramedian approach and landmark guided midline approach in elderly population (>60 years). [1] The successful dural puncture rate on first attempt was higher in landmark group (77%) and in pre-procedural ultrasound guided midline group (73%) than in pre-procedural ultrasound guided paramedian group (42%) with p value <0.001. They found lesser success rate on first attempt in the pre-procedural ultrasound paramedian group. This is because the procedure in this study was performed by junior residents. They concluded that pre-procedural ultrasound scan did not improve the ease of midline and paramedian spinal anaesthesia as compared to the conventional landmark technique midline technique when performed by junior residents in an elderly population.[1]

Srinivasan KK et al did a prospective, randomised, controlled study on 120 elderly patients scheduled for elective lower limb joint

arthroplasties and compared pre-procedural ultrasound-guided paramedian vs landmark guided midline approach for spinal anaesthesia.[27] They concluded that routine use of pre-procedural ultrasound guided paramedian spinal anaesthesia performed at the L5-S1 level did not reduce the number of passes or attempts required to achieve a successful dural puncture as compared to landmark guided midline approach.

Chin KJ et al performed a prospective descriptive, observational study on 50 elderly patients undergoing elective total joint arthroplasty under ultrasound assisted spinal anaesthesia.[19] The results of this study showed that pre-procedural ultrasound guided spinal anaesthesia in an elderly population is both feasible and potentially useful in identifying the lumbar intervertebral spaces and providing an accurate estimate of the depth of the intrathecal space.

Kumar Anil et al conducted a randomised study on 110 patients with BMI< 30 kg/m^2, undergoing lower limb orthopaedic surgery to compare ultrasound guided paramedian approach versus landmark guided midline technique.[28] The success rate of dural puncture in first attempt was 89.09% in ultrasound group as compared to 76.36% in landmark group. The time taken for spinal anaesthesia was higher (2.88±0.52 minutes) in landmark group as compared to in pre-ultrasound procedural group (2.59±0.5 minutes) which was statistically significant with p value 0.004. They concluded that the pre-procedural USG guided paramedian approach does not increase the success rate at first attempt significantly as compared to midline landmark guided approach, in patients with normal spine.

Lim YC et al did a prospective randomised controlled trial on 170 patients and compared the pre-procedural ultrasound guided paramedian approach with landmark paramedian approach.[14] The rate of successful dural puncture during the first attempt was 64% in ultrasound group and 52 % in lamdmark group and was statistically insignificant. The time taken to perform the procedure was lesser 2.9±3.6 minutes in pre-procedural ultrasound group as compared to 3.9±3.7 minutes in landmark group and was statistically significant with

p value 0.007. They concluded that the Pre-procedural ultrasound scanning is probably useful only for certain patients where traditional techniques for spinal anaesthesia are technically difficult.

Sherif A Abdelhamid et al designed a prospective observational study in 90 patients ASA I–II, age from 20– 60 years with normal spine scheduled to receive intrathecal anesthesia.[29] These patients were randomly allocated into 2 groups, Group I was the ultrasound group and Group II was the surface landmark group. They concluded that pre-procedural ultrasound scanning improved the first needle attempt success rate, decreased redirection or further attempts, and gave better patient satisfaction. This demonstrates the importance of routinely applying the ultrasound scanning preoperatively for better quality of spinal anaesthesia performance and better patient satisfaction.

After thorough literature search, we could find only few studies on use of real time ultrasonography for difficult spinal anatomy. Hence, we proposed to study and compare the paramedian approach for spinal anaesthesia with real time ultrasound guidance versus landmark technique in our patients with difficult spine anatomy.

MATERIALS AND METHODS

SOURCE OF DATA

A prospective, randomized study was conducted in the Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after approval by Institutional Ethics Committee. Seventy patients aged 18 years or more of either sex, American Society of Anaesthesiologists (ASA) grade I-III, with difficult spine anatomy, scheduled for elective surgeries under spinal anaesthesia were enrolled and randomly allocated into two study groups of 35 patients each. A written informed consent was obtained from each patient prior to the procedure.

METHOD OF COLLECTION OF DATA

Inclusion Criterion:

Patients more than 18 years and older who were scheduled for elective surgery under subarachnoid block, were considered eligible for enrolment if they have difficult spine anatomy as assessed by presence of any one of the following:

- Lumbar spine deformity: kyphosis, lordosis or scoliosis
- Poorly palpable or impalpable spinous processes.
- BMI ≥ 30 kg/m^2

Exclusion Criterion:

- Refusal for spinal anaesthesia
- Coagulopathy
- INR > 1.5, platelet count <100 x 10^9/L
- Local site infection
- Allergy to local anaesthetic drugs
- Patients having any contraindications to spinal anaesthesia

SAMPLE SIZE

Sample size was estimated from the results of previous study[17] using the first attempt success rate as the parameter, which was the primary outcome of our study.

Our sample size came out to be 35 subjects per group at power of 0.98 and with an effect size of 1.81 with 10% chance of error with $\alpha = 0.05$, $\beta = 0.20$ and confidence interval of 95%.

A post hoc power analysis was conducted using the software package, G*Power version 3.1.9.2 (Franz Faul, university kiel, Germany). The alpha level used for this analysis was $p<0.05$ and beta was 0.20.

Randomization and group allocation-

A total of 70 patients were randomized into two groups of 35 patients each. Randomization was done by computer generated randomization codes contained in sealed, sequentially numbered envelopes.

- Group A - Patients received spinal anaesthesia by conventional surface landmark- guided paramedian technique.
- Group B - Patients received spinal anaesthesia by an ultrasound guided paramedian technique.

Methodology

PREANAESTHETIC CHECKUP

A thorough history and physical examination was done. Baseline patient's characteristics such as; age, gender, BMI, presence of any spinal abnormalities and history of any spinal surgery in past were recorded. Routine investigations were done in all patients according to institutional protocol.

A written informed consent was obtained from all the patients. After arrival of the patient to operation theatre, standard monitoring was done (Electrocardiogram, non-invasive blood pressure measurement and oxygen saturation). Intravenous access was established in all patients. Pre-procedure and post-procedure vitals were recorded.

ANAESTHESIA TECHNIQUE

Patients were positioned in a sitting posture with back flexed. Under all aseptic precautions a large area of lumbo-sacral spine was painted using antiseptic solution. In group A, surface anatomic landmarks were palpated to determine the location of paramedian lumbar intervertebral space and time taken was recorded as assessment time. Lidocaine 2% was used for skin infiltration. Spinal anaesthesia was performed in best palpable space between L2- L5 using standard paramedian approach by an anaesthesiologist with more than 5 years of clinical experience, using a 23-gauge Quinke needle. The time between start of needle

insertion and achievement of free flow of CSF was noted as procedure time. Total procedure time was calculated as sum of assessment time and the procedure time.

In group B, with patient in sitting position and under all aseptic precautions, ultrasound imaging of the lumbar spine using a SonoSite Edge II Total (SH Serial number 04N1DC) ultrasound machine and a low-frequency (2–5 MHz) curved-array probe was done. Anaesthesiologist who had an experience of more than 30 ultrasound-guided subarachnoid blocks performed the procedure in all patients. Probe was applied to the patient's back in the paramedian plane. The sacrum was identified first and then the probe moved cephalad in the paramedian axis and tilted 10–15 degree towards midline. The lumbar lamina and interlaminar spaces between L2-3, L3-4 or L4- L5 was identified. Then the probe was positioned with its midline point directly above the intervertebral space. The transducer was then rotated 45 degrees towards midline, into an oblique, paramedian sagittal view. The quality of scan in parasagittal oblique view was graded on basis of visualization of ligamentum flavum/dura mater complex (LFD) and posterior longitudinal ligament (PLL). It was either graded as good (both LFD and PLL visible) or intermediate (either LFD or PLL visible) else poor (both LFD and PLL not visible). The level/space at which the quality of scan was best, was chosen as target space for needle insertion. The time taken from the placement of probe to identification of best space was recorded as assessment time. Lidocaine 2% was used for skin infiltration. Quinke needle (23 gauge) was then inserted in plane from the caudal end of the ultrasound transducer with its tip directed towards the interlaminar space. The needle was advanced gradually to the interlaminar space, under real time in-plane ultrasound guidance, until pierced through the ligamentum flavum/dura mater complex. Stylet was then withdrawn to confirm free flow of CSF. The time taken between starting of needle insertion and achievement of CSF was recorded and termed as procedure time. Total procedure time was calculated as sum of assessment time and procedure time.

After achieving successful dural puncture as confirmed by free flow of cerebrospinal fluid from the needle hub, intrathecal anaesthetic solution was injected in both groups. Both the ultrasound guided and surface landmark guided spinal anaesthesia were performed by the same anaesthesiologist.

A total of six attempts (needle insertion plus redirection attempts) were allowed. Needle insertion attempt was defined as number of separate skin punctures made by needle while needle redirection attempt was defined as any change in needle insertion trajectory that does not involve complete withdrawal of needle from the patient's skin. The anaesthesiologist was given the discretion to attempt in a different lumbar intervertebral space if deemed necessary, which was recorded. If dural puncture was unsuccessful even after six attempts (needle insertion plus redirection attempts), then it was considered as failed attempt. The anaesthetist had the option to use alternate techniques including a senior anaesthesiologists help, midline approach with landmark or ultrasound guided technique or general anaesthesia.

After completion of procedure, patients were asked to rate the pain in back during administration of spinal anaesthesia, using 11-point numeric rating scale (0-10) in both groups (0 – no pain, 10- worst pain). Discomfort during the overall neuraxial procedure was noted on six point numeric rating scale , based on any uncomfortable feeling due to positioning, anxiety, or fear in both groups (0 – no discomfort 5 - worst discomfort).

Outcome:

The primary outcome of our study was:

- To compare the first needle insertion attempts required for successful acquisition of CSF with both the techniques.

The secondary outcomes were:

- To compare the number of needle insertion attempts and needle redirections required for successful dural puncture in both groups.
- To compare the total procedure time.
- To compare peri-procedural pain, discomfort scores and complications if any.

Statistical Analysis

Data was described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups was done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively. For comparing categorical data, Chi square ($\chi 2$) test was performed and exact test was used when the expected frequency was less than 5. A probability value (p value) less than 0.05 was considered as statistically significant. All statistical calculations were done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

OBSERVATIONS AND RESULTS

This study was conducted in a prospective randomized manner in Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana on 70 patients of either sex, more than 18 years of age, with difficult spine anatomy belonging to ASA grade I, II & III scheduled for elective surgeries under spinal anesthesia.

The study aimed to compare the first needle insertion attempts required for successful acquisition of CSF with real time ultrasound guided versus landmark guided paramedian approach.

- Group A- 35 patients received spinal anaesthesia by conventional surface landmark guided paramedian technique.
- Group B- 35 patients received spinal anaesthesia by a real time ultrasound guided paramedian technique.

The observations of our comparative study are as follows:

DEMOGRAPHIC PROFILE

Table 1: Distribution of patients according to age, height, weight and BMI.

	Group A		Group B		T	p-value
	Mean	SD	Mean	SD		
Age (years)	49.80	14.03	55.17	14.72	-1.563	0.123
Height (cm)	166.29	10.07	167.17	7.82	-0.411	0.682
Weight (kg)	95.40	13.65	97.77	14.09	-0.715	0.477
BMI (kg/m^2)	34.45	3.46	34.91	3.90	-0.529	0.598

Both the groups were statistically comparable in terms of age, height, weight and BMI with p value >0.05

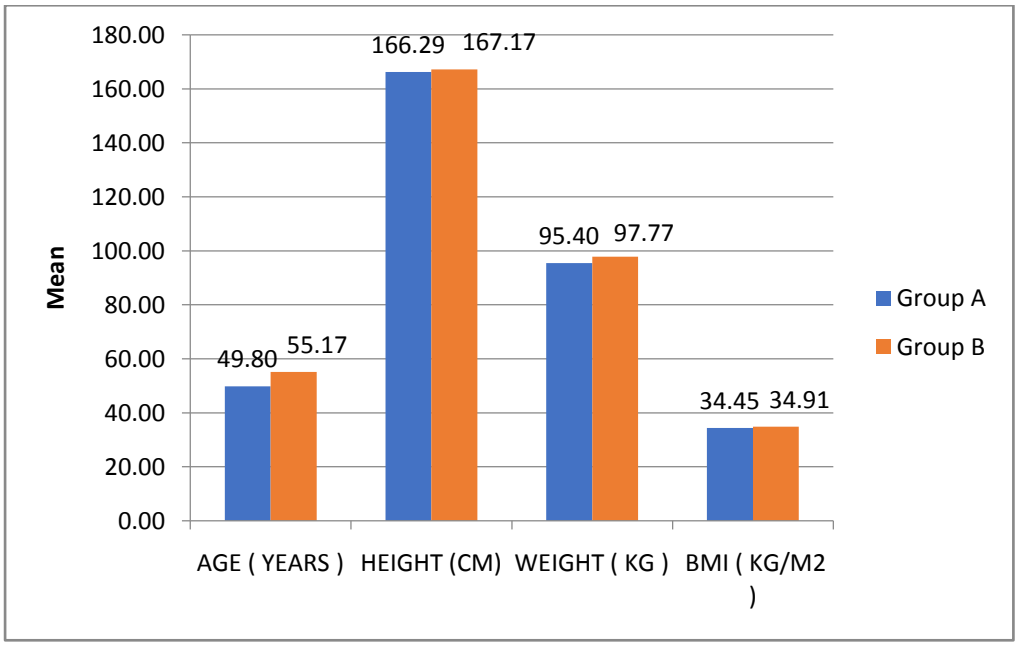

Figure 1: Distribution of patients according to age, height, weight and BMI.

Table 2: Distribution of patients according to sex, ASA grading, anatomy of spine and history of spine surgery.

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	Percentage	No. of cases	Percentage			
Sex	Female	11	31.4%	11	31.4%	22	0.000	1.000
	Male	24	68.6%	24	68.6%	48		
ASA Grade	1	5	14.3%	3	8.6%	8	0.643	0.725
	2	13	37.1%	15	42.9%	28		
	3	17	48.6%	17	48.6%	34		
H/o spine surgery	No	35	100.0%	35	100.0%	70	0.000	1.000
	Yes	0	0.0%	0	0.0%	0		
Lumbar spine deformity	Absent	35	100.0%	35	100.0%	70		
Spinous processes	Impalpable	22	62.9%	20	57.1%	42	0.238	0.626
	Poorly palpable	13	37.1%	15	42.9%	28		
	Total	35	100.0%	35	100.0%	70		

Both the groups were comparable with respect to sex, ASA grading, history of spine surgery, lumbar spine deformity and palpability of spinous processes.

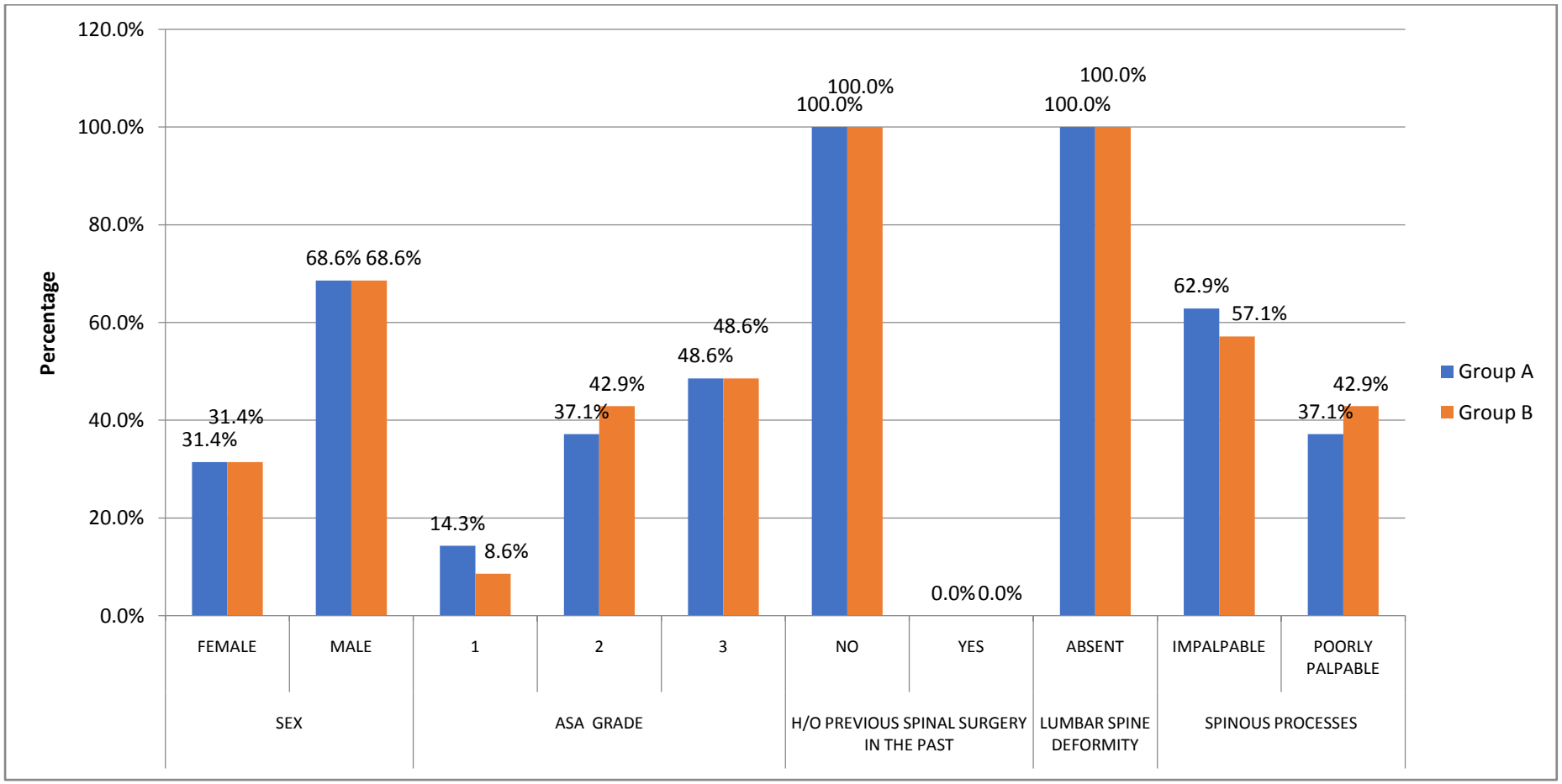

Figure 2: Distribution of patients according to sex, ASA grading, anatomy of spine and history of spine surgery.

Table 3: Distribution of patients according to number of needle insertions.

	Group A		Group B		Total	Chi-square value	p-value
Number of needle insertions	No. of cases	Percentage	No. of cases	Percentage			
1	18	51.4%	34	97.1%	52	19.145	0.001
2	17	48.6%	1	2.9%	18		
Total	35	100.0%	35	100.0%	70		
Mean± SD	1.49±0.51		1.03±0.17		-	z	p-value
Median(IQR)	1(1-2)		1(1-1)		-	-4.344	0.001

In group B, only one needle insertion was required for successful dural puncture in majority patients except one where two needle insertions were required. In group A, 18 patients required one needle insertion and 17 patients required two needle insertions for successful dural puncture. The number of needle insertions were lower in group B as compared to group A and this difference was statistically significant with p value 0.001.

The mean number of needle insertions were lower in group B 1.03(±0.17) as compared to group A 1.49(±0.51), which was statistically significant with p value 0.001.

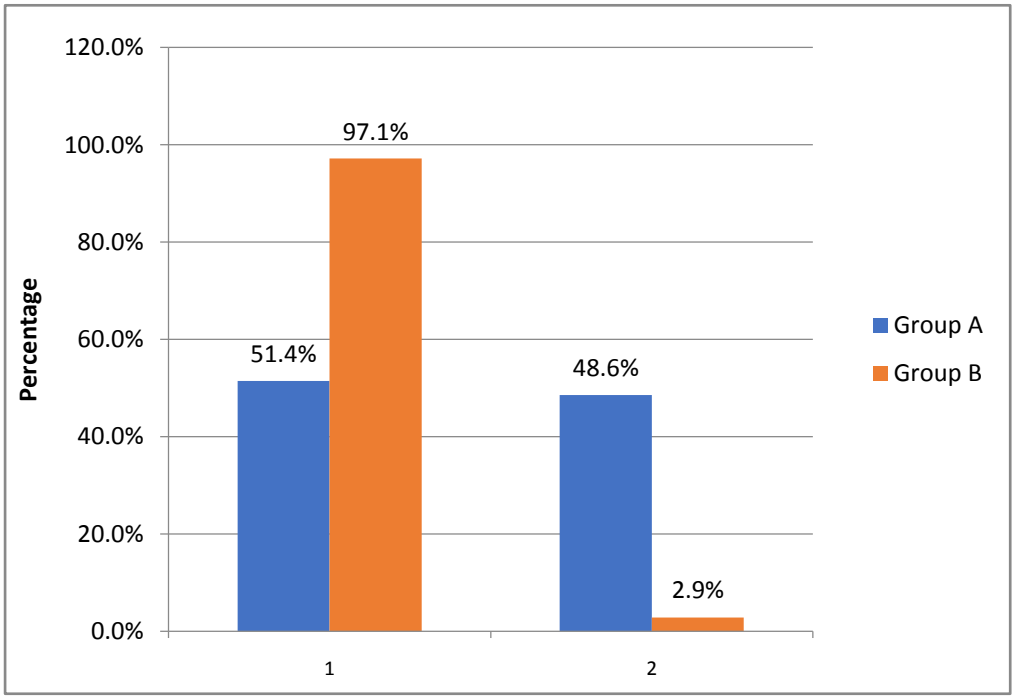

Figure 3: Distribution of patients according to number of needle insertions.

Table 4: Distribution of patients according to number of needle redirections.

Number of needle redirections	Group A		Group B		Total	Chi-square value	p-value
	No. of cases	Percentage	No. of cases	Percentage			
0	4	11.4%	14	40.0%	18	7.478	0.006
1	10	28.6%	7	20.0%	17	0.699	0.403
2	9	25.7%	7	20.0%	16	0.324	0.569
3	8	22.9%	7	20.0%	15	0.085	0.771
4	4	11.4%	0	0.0%	4	4.242	0.039
Total	35	100.0%	35	100.0%	70	10.402	0.034
Mean± SD	1.94±1.21		1.20±1.18			Z	p-value
Median(IQR)	2(1-3)		1(0-2)			-2.450	0.014

In group B 40 % and in group A 11.4% patients required no needle redirections which was statistically significant with p value 0.006.In group A 11.4% patients required 4 needle redirections whereas in group B none of the patients required more than 3 needle redirections. This difference was statistically significant with p value 0.039. Both groups were comparable with regards to 1 to 3 needle redirections with p value >0.05

The median number of needle redirections were less in group B [1(0-2)] as compared to group A[2(1-3)] which was statistically significant with p value 0.014

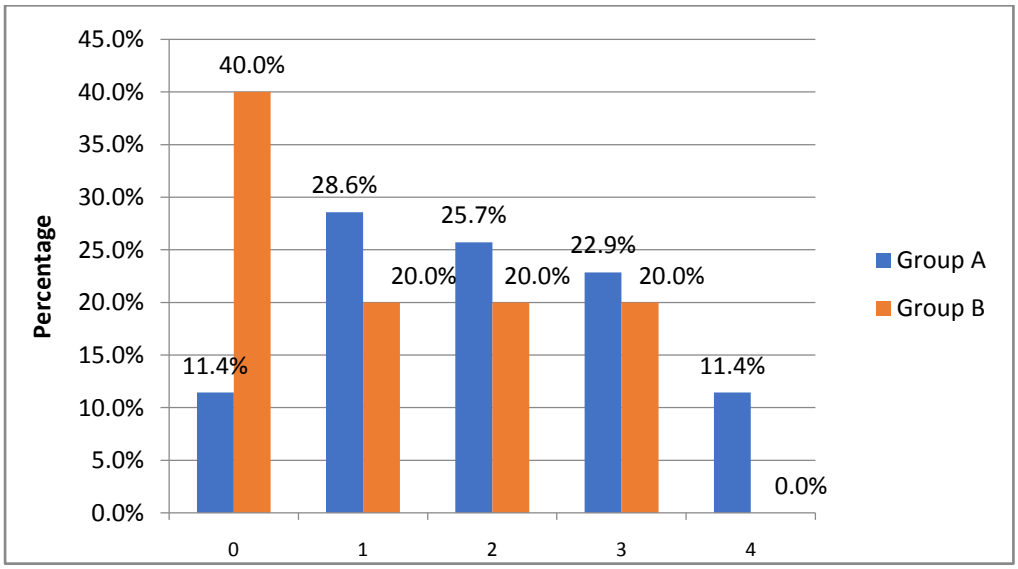

Figure 4: Distribution of patients according to number of needle redirections.

Table 5: Distribution of patients according to number of total attempts.

	Group A		Group B		Total	Chi-square value	p-value
Total attempts	No. of cases	Percentage	No. of cases	Percentage			
1	4	11.4%	14	40.0%	18	7.478	0.006
2	7	20.0%	7	20.0%	14	0.000	1.000
3	7	20.0%	6	17.1%	13	0.094	0.756
4	8	22.9%	8	22.9%	16	0.000	1.000
5	5	14.3%	0	0.0%	5	5.385	0.020
6	4	11.4%	0	0.0%	4	4.242	0.039
Total	35	100.0%	35	100.0%	70	14.632	0.012
Mean± SD	3.43±1.54		2.23±1.21			Z	p-value
Median(IQR)	3(2-5)		2(1-3)			-3.231	0.001

The incidence of successful dural puncture on first attempt was significantly higher in group B (40.0%) as compared to group A (11.4%) (p value 0.006).

In group B, successful dural puncture was achieved in all the patients within 4 total attempts (needle insertion + needle redirection) as compared to 6 total attempts required in group A. In group A, 5 patients required five and 4 patients required six attempts for successful dural puncture and it was statistically significant with p value 0.020 and 0.039 respectively when compared with group B.

The mean number of total attempts (which include needle insertion plus needle redirection) were lower in group B 2.23(±1.21) than in group A 3.43(±1.54), which was statistically significant with p value 0.001.

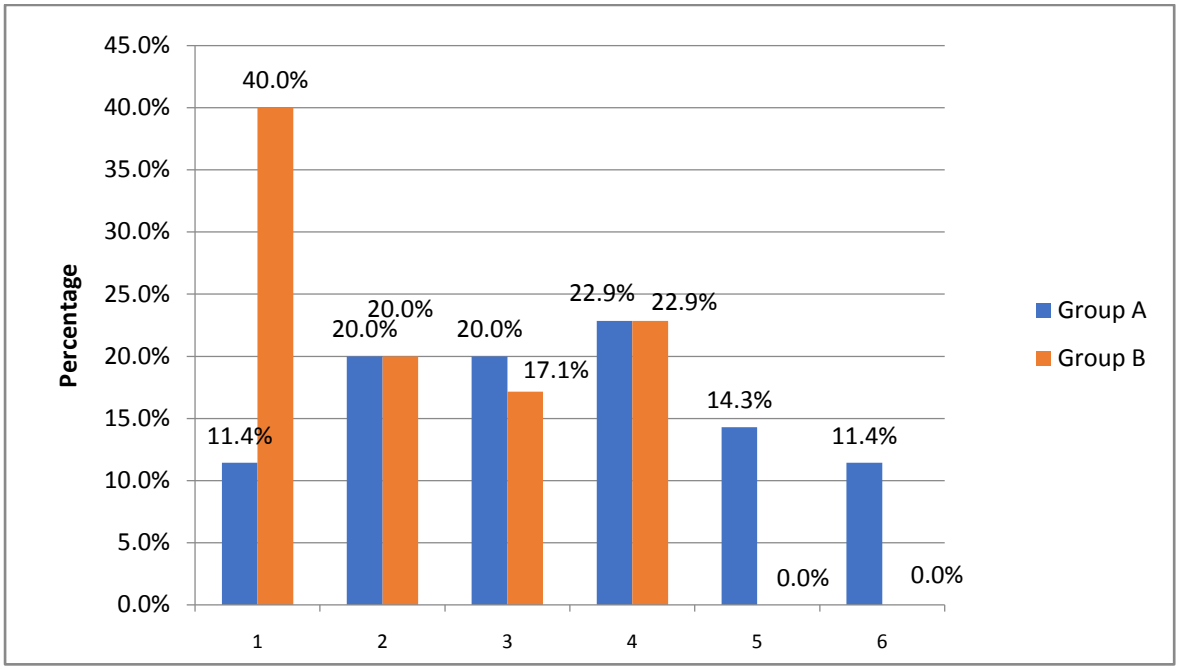

Figure 5a: Distribution of patients according to total attempts.

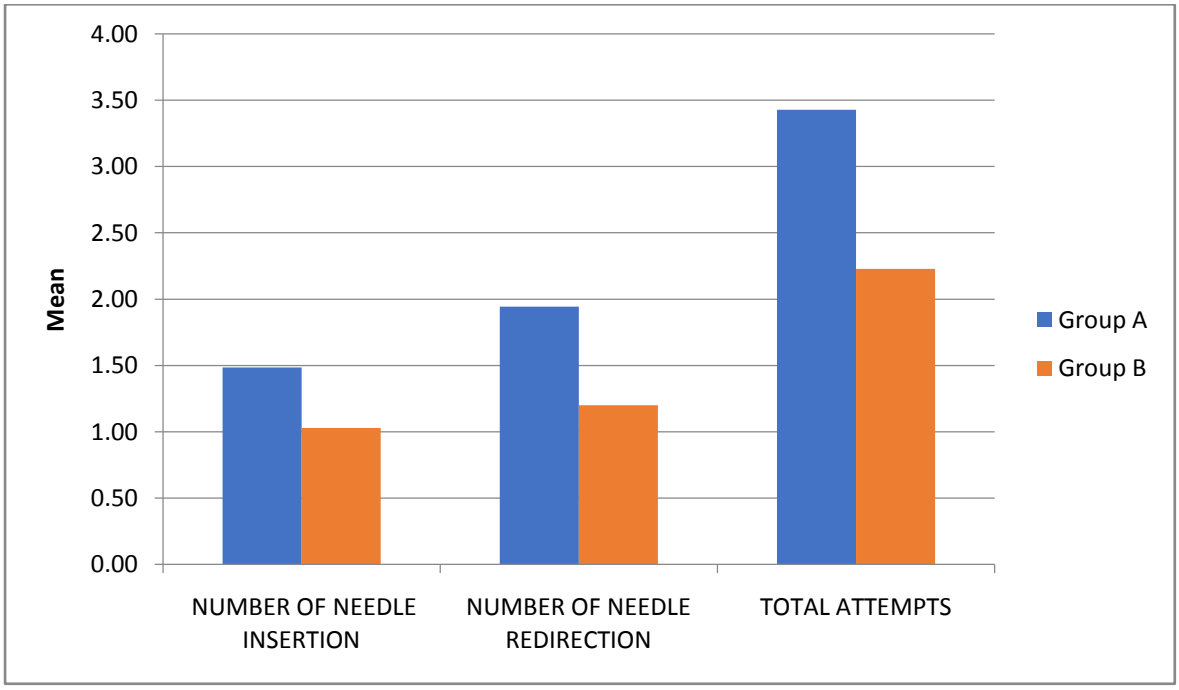

Figure 5b: Distribution of patients according to needle insertion, redirection and total attempts.

Table 6: Distribution of patients according to change in level of paraspinal space.

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	Percentage	No. of cases	Percentage			
Change in level of paraspinal space	Yes	8	22.9%	1	2.9%	9	6.248	0.012
	No	27	77.1%	34	97.1%	61		
Change in level of paraspinal space								
L2-L3 to L3-L4		0	0.0%	0	0.0%	0	0.000	1.000
L3-L4 to L4-L5		4	11.4%	1	2.9%	5	1.938	0.164
L4-L5 to L2-L3		1	2.9%	0	0.0%	1	1.014	0.314
L4-L5 to L3-L4		3	8.6%	0	0.0%	3	3.134	0.239

In group A, change in level of paraspinal space had to be done in 22.9%. In 11.4% patients it was changed from L3-L4 to L4-L5, in 2.9 % patients from L4-L5 to L2-L3 and in 8.6 % patients from L4-L5 to L3-L4. In group B only in 2.9% patients it was changed from L3-L4 to L4-L5 for successful dural puncture. There was statistically significant difference present in both the groups with regards to change in level of paraspinal space with p value 0.012.

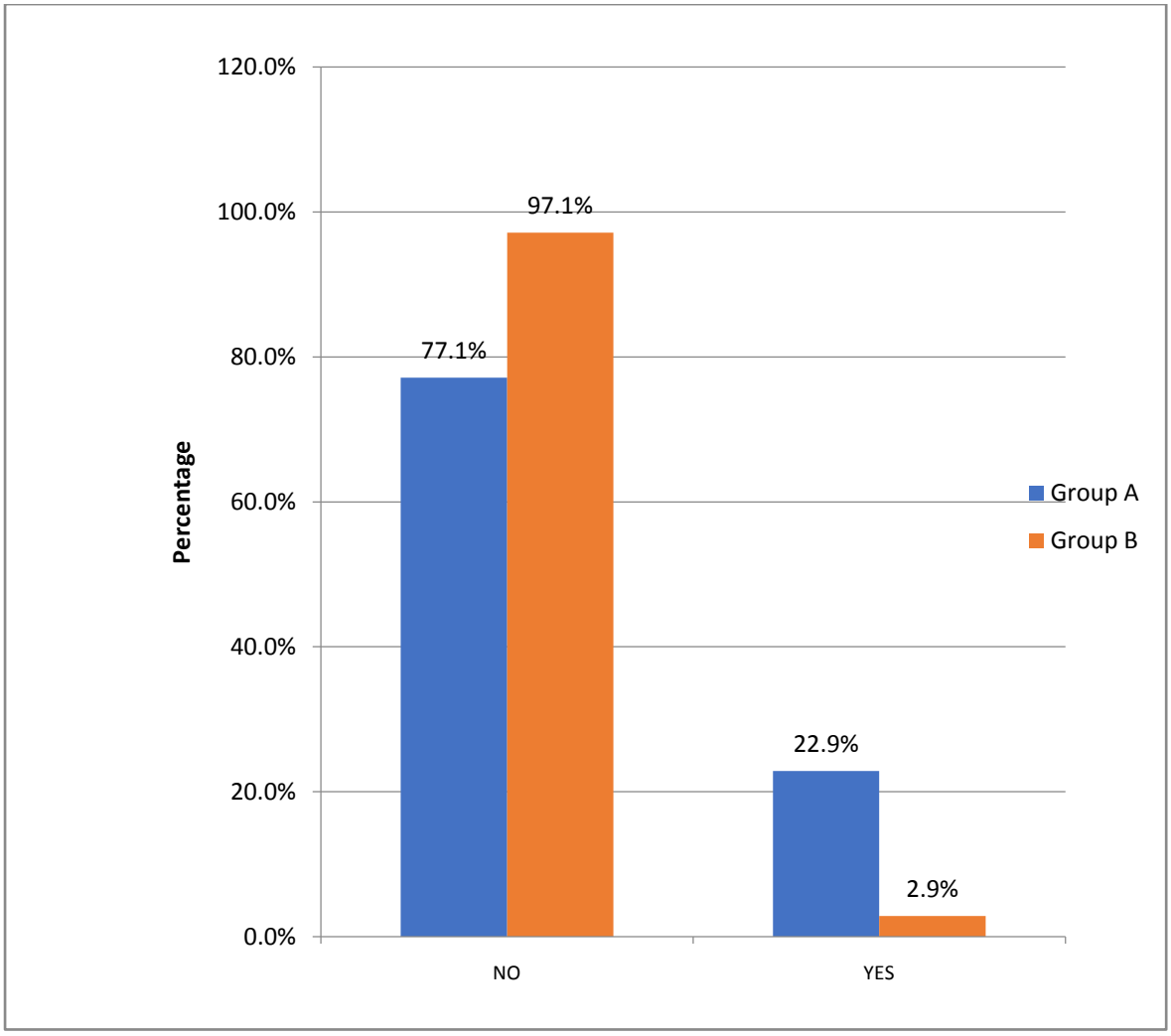

Figure 6: Distribution of patients according to change in paraspinal space.

Table 7:Distribution of patients according to assessment time and procedure time.

	Group A		Group B		Z	p-value
	Mean± SD	Median(IQR)	Mean± SD	Median(IQR)		
Assessment time (Seconds / Minutes)	29.97±9.72 sec	30(20-40) sec Or 0.5 (0.33-0.66)min	155.83±37.59 sec	150 (130-180) sec Or 2.5 (2.1-3) min	-7.212	0.001
Procedure time (Seconds / Minutes)	84.77±27.96sec Or 1.42±0.46min	80(70-90) sec	41.49±13.15sec Or 0.67±0.21 min	40(30-50) sec	-6.471	0.001
Total procedure time (Seconds / Minutes)	112.66±38.78 sec Or 1.88±0.65 min	110(99-130) sec	197.31±48.26 sec Or 3.29±0.80 min	190(170-230) sec	-6.009	0.001

The mean time taken to identify the anatomical landmarks (assessment time) in group B was higher [155.83 (±37.59)sec] than in group A [29.97(±9.72)sec] which was statistically significant with p value 0.001. The median time taken to identify the anatomical landmarks in group B was higher [2.5 (2.1-3) min] than in group A [0.5 (0.33-0.66) min] which was statistically significant with p value 0.001.

The mean time taken for spinal anaesthesia (procedure time) in group A [1.42±0.46min] was significantly higher as compared to that in group B (0.67±0.21) min which was statistically significant with p value 0.001.

Mean total procedure time was longer in group B [3.29±0.80min] as compared to group A [1.88±0.65 min] which was statistically significant with p value 0.001.

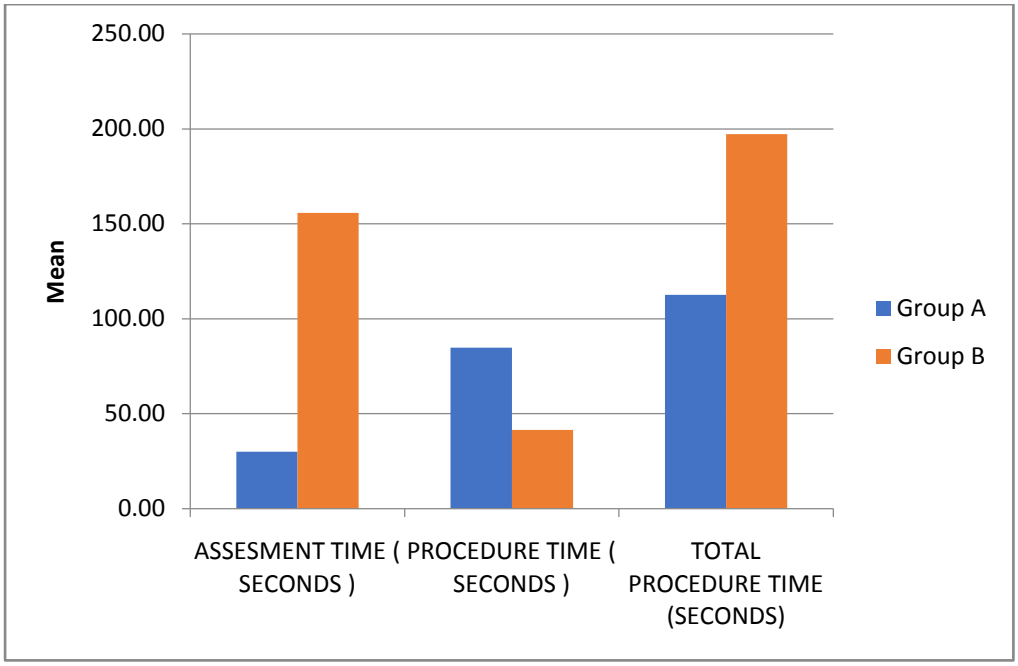

Figure 7: Distribution of patients according to assessment time and procedure time.

Table 8: Distribution of patients according to peri-procedural pain score.

	Group A		Group B		Total	Chi-square value	p-value
Peri procedural pain score (0-10)	No. of cases	Percentage	No. of cases	Percentage			
< 4	23	65.7%	27	77.1%	50	1.12	0.289
> 4	12	34.3%	8	22.9%	20		
Total	35	100.0%	35	100.0%	70		

Both the groups were statistically comparable with respect to peri-procedural pain score.

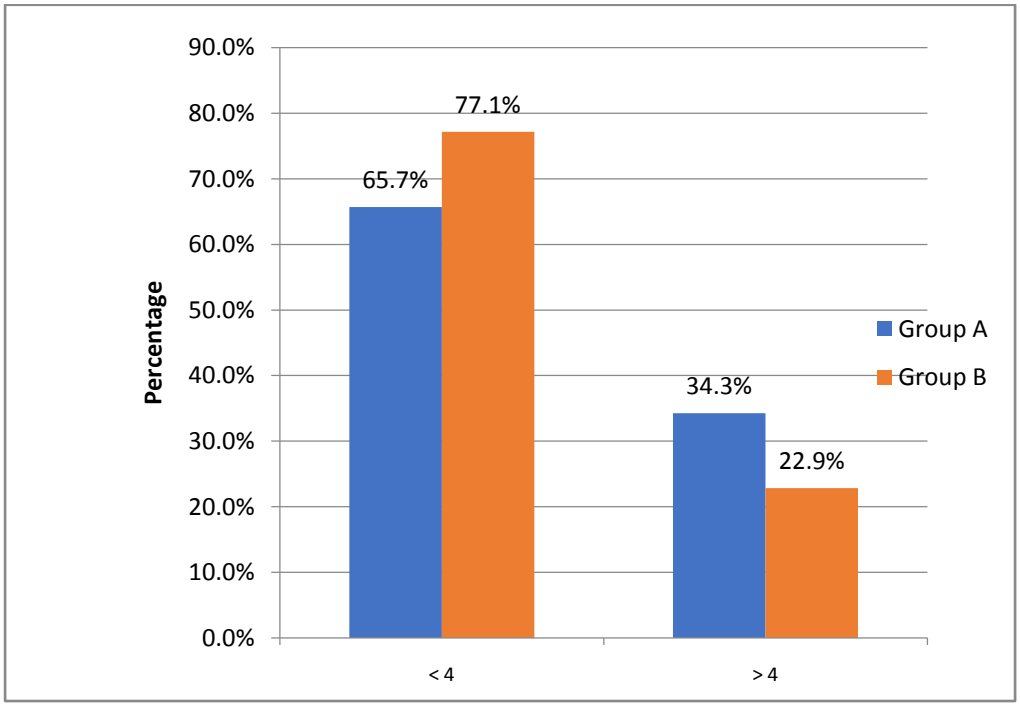

Figure 8: Distribution of patients according to peri-procedural pain score.

Table 9: Distribution of patients according to peri-procedural discomfort score.

	Group A		Group B		Total	Chi-square value	p-value
Peri-procedural discomfort score (0-5)	No. of cases	Percentage	No. of cases	Percentage			
< 2	23	65.7%	31	88.6%	54	5.185	0.023
> 2	12	34.3%	4	11.4%	16		
Total	35	100.0%	35	100.0%	70		

In group A 34.3% and in group B 11.4% patients had a peri-procedural discomfort score of >2 which was statistically significant with p value 0.023.

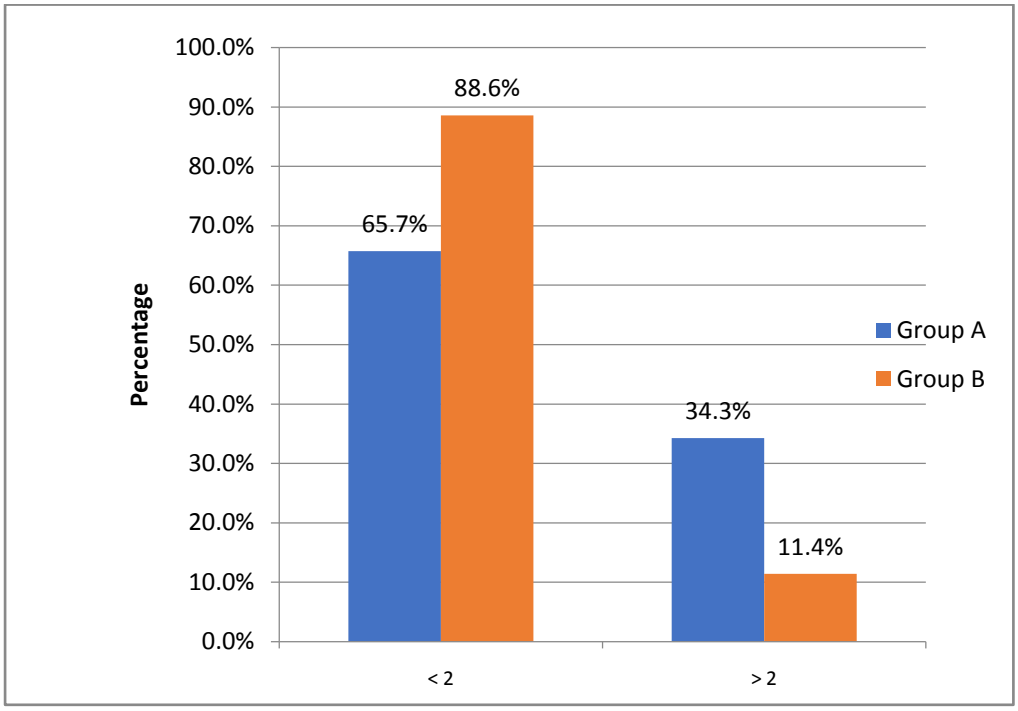

Figure 9: Distribution of patients according to peri-procedural discomfort score.

Table 10: Distribution of patients according to Complications.

Complications		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	Percentage	No. of cases	Percentage			
Bloody tap	No	32	91.4%	34	97.1%	66	1.061	0.614
	Yes	3	8.6%	1	2.9%	4		
Paresthesia	No	35	100.0%	35	100.0%	70		

Traumatic puncture was present in 8.6% patients in group A and 2.9% patients in group B, which was statistically non significant with p value 0.614.

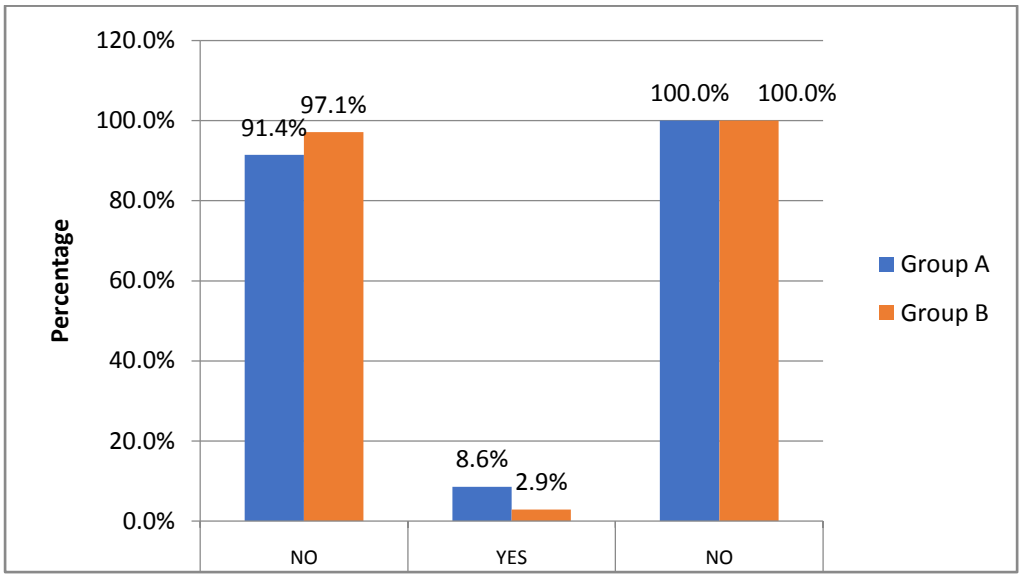

Figure 10: Distribution of patients according to Complications.

Table 11: Distribution of patients according to failure of technique and conversion of technique.

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	Percentage	No. of cases	Percentage			
Failure of Technique	No	34	97.1%	35	100.0%	69	1.014	0.314
	Yes	1	2.9%	0	0.0%	1		
Landmark guided to ultrasound guided technique		1	2.9%	0	0.0%	1	1.014	0.314
Ultrasound guided to landmark guided technique		0	0.0%	0	0.0%	0		
Conversion to general anesthesia		0	0.0%	0	0.0%	0		

In group A in one patient, even after six attempts we were unable to achieve successful dural puncture and according to our study protocols the technique was then changed from landmark guided to ultrasound guided technique.

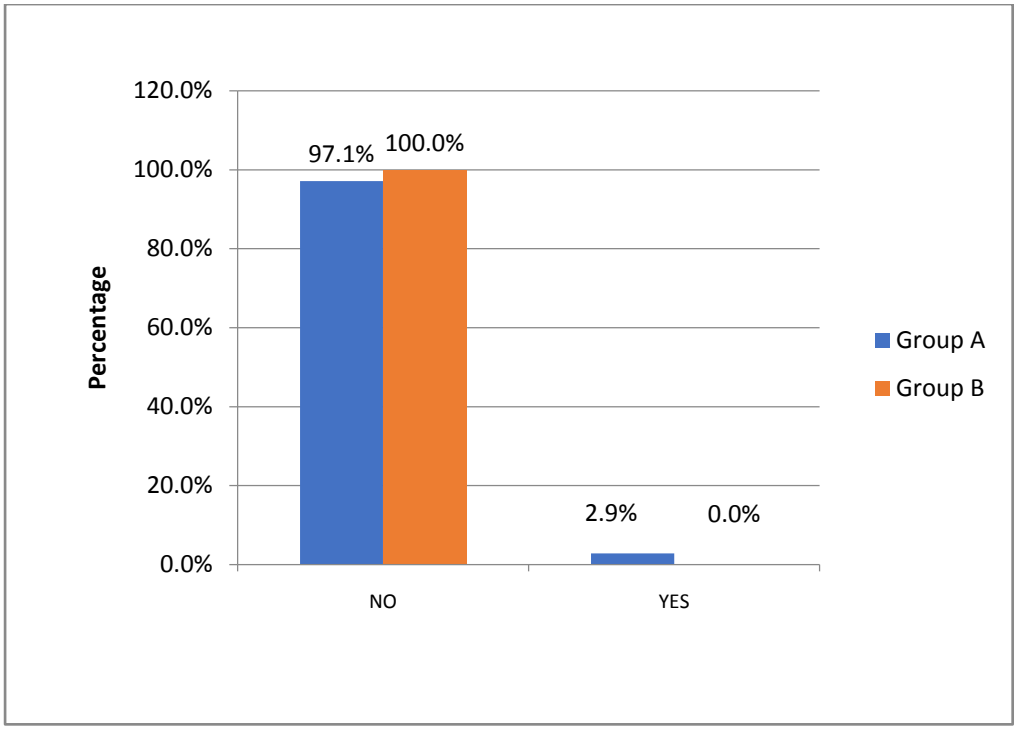

Figure 11a: Distribution of patients according to failure of technique.

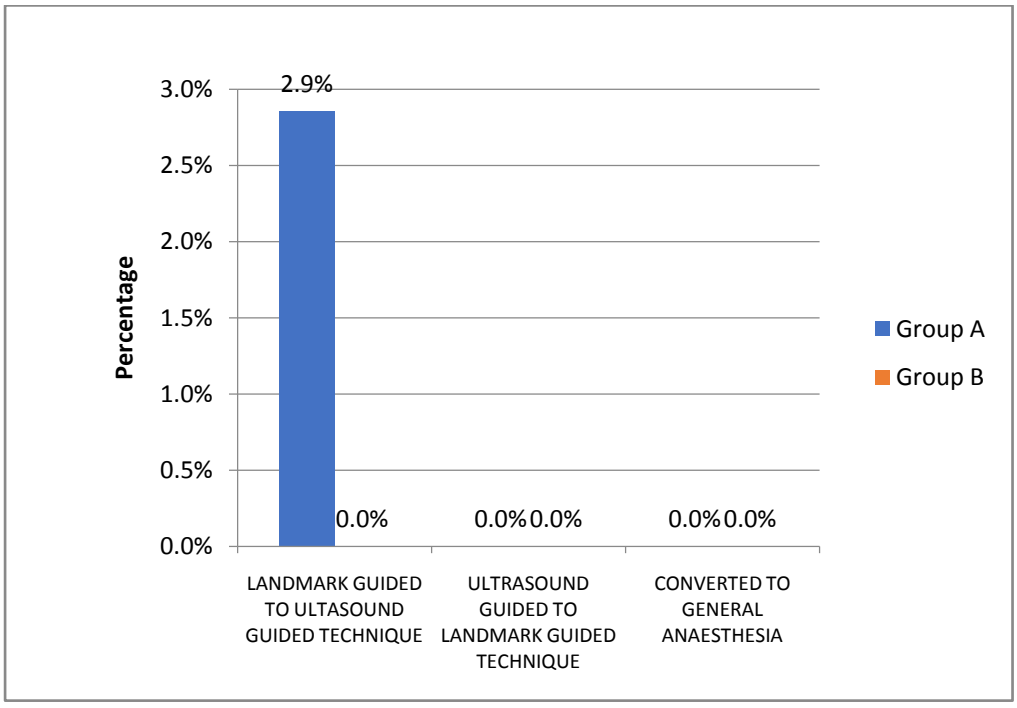

Figure 11b: Distribution of patients according to conversion of technique.

Table 12: Distributions of patients according to grading of anatomical surface landmarks.

	Group A	
Grading of anatomical surface landmarks	No. of cases	%age
Palpable	0	0.0%
Poorly Palpable	12	34.3%
Unpalpable	23	65.7%
Total	35	100.0%

In landmark group, the anatomical surface landmarks were unpalpable in 65.7% patients and poorly palpable in 34.3% patients .

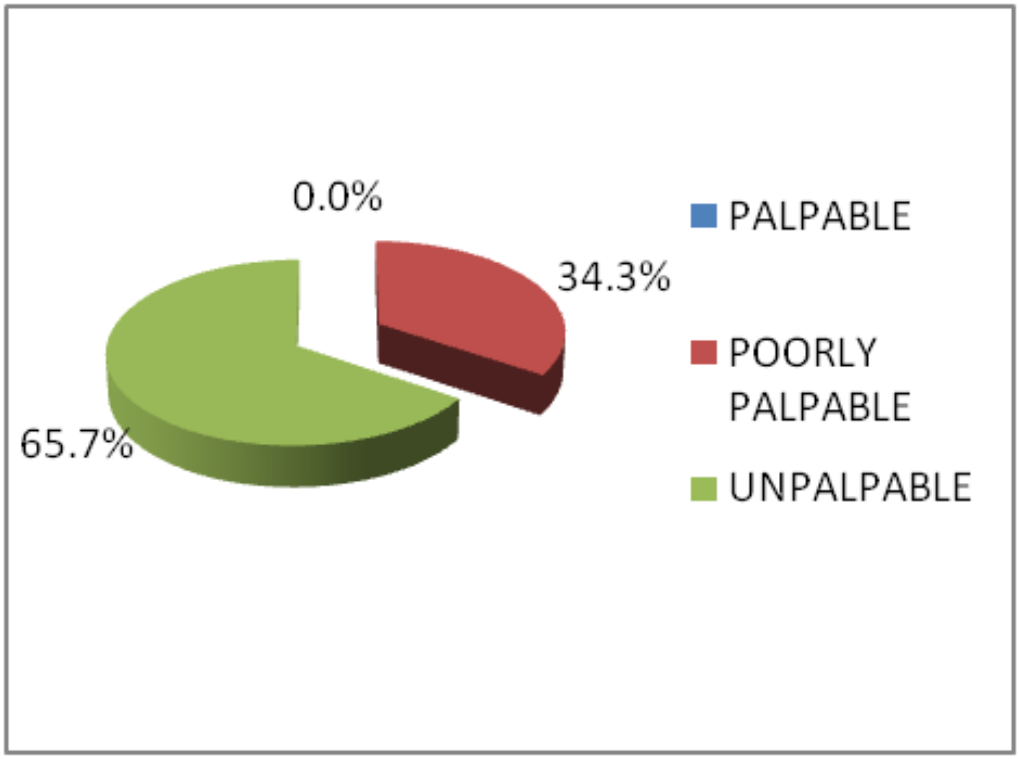

Figure 12: Distributions of patients according to grading of surface anatomical landmarks.

Table 13: Distribution of patients according to best quality of space in ultrasound scan and view of ultrasound guided technique.

Group B		
Best quality of space in ultrasound scan	No. of cases	%age
L2-L3	0	0.0%
L3-L4	26	74.3%
L4-L5	9	25.7%
Group B		
View of ultrasound guided technique	No. of cases	%age
Good	13	37.1%
Intermediate	8	22.9%
Poor	14	40.0%
Total	35	100.0%

In ultrasound scan, best quality of intervertebral space visualized was L3-L4 in 74.3% patients of group B. While in 25.7% patients L4-L5 was the best space visualized.

The quality of scan in parasagittal oblique view was graded on the basis of visualization of ligamentum flavum dura mater (LFD)and posterior longitudinal ligament (PLL). It was good in 34.3% patients, intermediate in 22.9% patients and poor in 40.0% patients.

and poor in 40.0% patients.

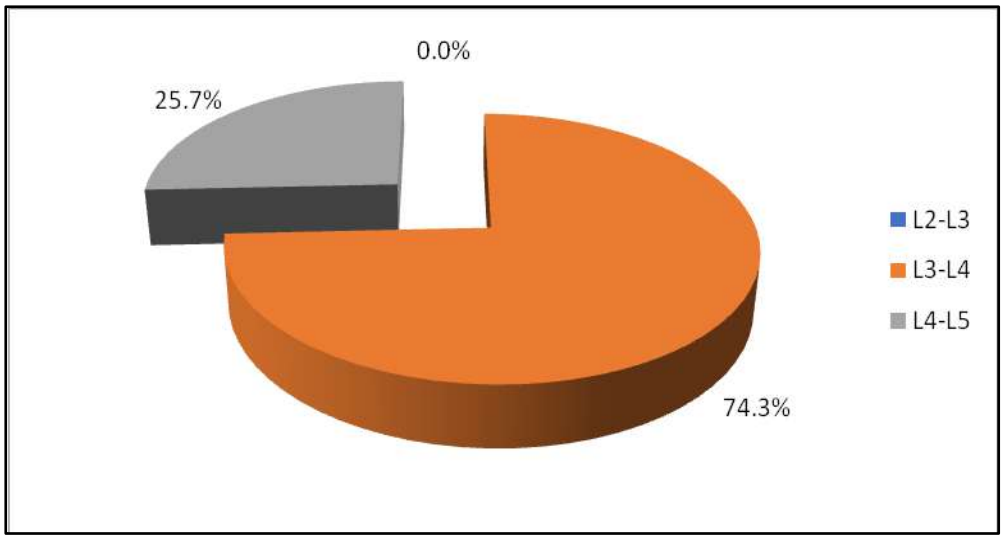

Figure 13a: Distribution of patients according of best quality of space in ultrasound scan.

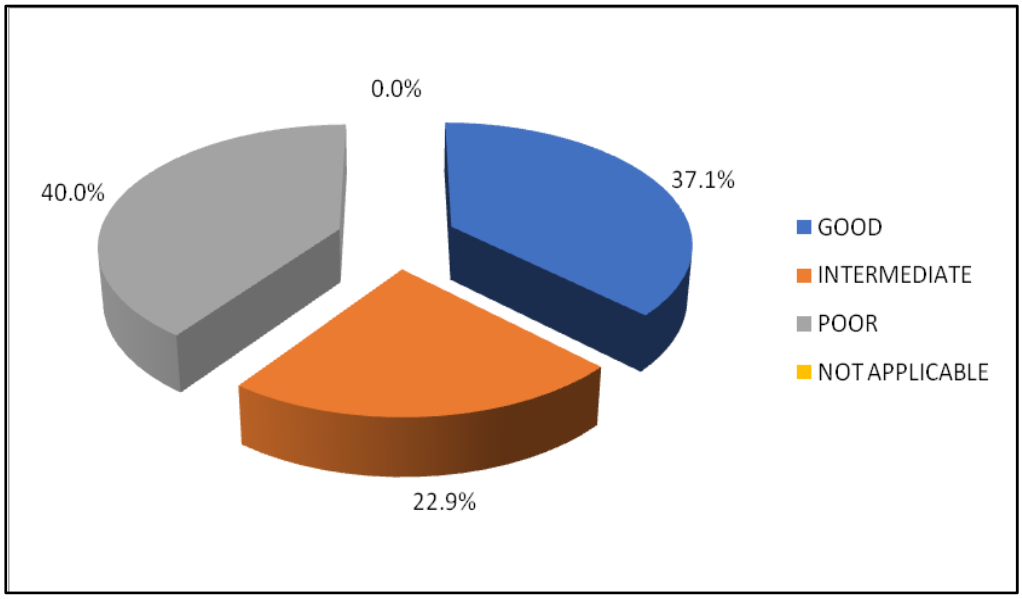

Figure 13b: Distribution of patients according to view of ultrasound guided technique.

DISCUSSION

Spinal anaesthesia has been conventionally performed using a surface landmark guided midline approach. However, it can be difficult in patients with spinal deformities like kyphosis, scoliosis, previous spinal surgeries, obesity, degenerative changes associated with ageing, where surface landmarks are either absent, indistinct or distorted.[5,23] It is desirable to decrease the technical difficulty of the neuraxial blockage because multiple needle insertion attempts and needle passes may increase the risk of complications such as inadvertent dural puncture, vascular puncture, epidural hematoma, post dural puncture headache, patient discomfort and paraesthesia.[5-10] The failure rate of neuraxial anaesthesia in patients with anticipated difficult spine is high.[15,30-32]

Ultrasound can help in understanding the underlying anatomy of patient's spine, particularly who have anatomical abnormalities that cannot be appreciated by surface landmarks and enhance the technical performance of spinal anaesthesia.[26,33-36] Pre-procedural ultrasonography of the spine has shown to reduce the number of attempts and needle passes by predicting technical difficulties in patients with difficult spine anatomy.[5,15,24,35,37] The chief limitation of pre-procedural ultrasound guided technique is that the anaesthesiologist remains blind during the actual needle insertion , andthus may still experience difficulty in directing the needle through the interlaminar space.[20] The Real time Ultrasonography (RUS) makes it possible to estimate the ideal needle insertion position and trajectory with more accuracy.[23]

Only limited studies are available regarding the use of real time ultrasound guided spinal anaesthesia technique. So, this prospective randomized study was planned to compare the efficacy of RUS guided paramedian approach spinal anaesthesia (group B) with conventional landmark guided paramedian approach spinal anaesthesia (group A) in patients with difficult spine anatomy.

The parasagittal oblique (interlaminar) view (PSO view) and the transverse interlaminar/interspinous view (TI view) are the most important views in clinical practice since they provide a view of the neuraxial structures through acoustic windows.[38] We chose to use the paramedian approach instead of midline approach to perform spinal anaesthesia because the PSO view allows for a wider ultrasound window of the epidural spaces, providing an enhanced visibility of the neuraxial and surrounding structures compared to the transverse median view.[1,39]

Both the groups were statistically comparable with respect to demographic data, ASA grade, history of spine surgery, lumbar spine deformity and grading of the surface anatomical landmarks according to spinous processes.

The primary outcome of our study was to compare the first needle insertion attempts required for successful acquisition of CSF, between both the techniques. The Real time ultrasound guided paramedian group had a higher success rate (40.0%) of dural puncture in first needle insertion attempt as compared to the conventional surface landmark guided paramedian technique group (11.4%) and this was statistically significant with p value 0.006. Ravi PR et al observed 60% success rate of dural puncture during the first needle insertion with use of real time ultrasound in their obese patients (BMI > 30kg/m2) which is in accordance with our study.[23] Our results are also consistent with study done by Chong SE et al in which success rate of dural puncture on single needle pass was higher in real time ultrasound group (47%) than in landmark group (20%).[11]

Bhardwaj D et al in their study on 150 patients aged 20-65 years with BMI of 18.5 – 29.9 kg/m2 had success rate of 80% on 1st needle insertion in real time ultrasound group and 82% in landmark group.[22] This variation from our study could be due to the fact that patients in their study had lower BMI (mean 23.85±3.03) with normal spine in contrast to our study where patients had higher BMI (34.91±3.90).The lower success rate with landmark technique in our study can be attributed to difficulty in palpability of the spinous processes. The

spinous processes were impalpable in 65.7% patients and poorly palpable in 34.3% patients in our study.

Amongst secondary outcomes, we mainly focused on the difference in total number of attempts (needle insertions plus needle redirections) required for successful dural puncture, the total procedure time (assessment time plus procedure time), peri-procedural pain and discomfort scores and complications, if any between both the groups.

In our study, the mean number of needle insertions was lower in group B 1.03 (±0.17) as compared to group A 1.49 (±0.51) which was statistically significant with p value 0.001. This is consistent with the study conducted by Bhardwaj D et al where mean number of needle insertions for the successful SAB was lower in real time ultrasound group [1.03± 0.26] than in landmark group [1.05± 0.35].[22] Similarly, in another study by Elsharkawy et al on patients with anticipated difficult anatomy of spine, the mean number of needle insertions for successful dural puncture were lower in the real time ultrasound group (1.4±0.6) than in the landmark group (1.6±1.1).[15]

In a study done by Narkhede et al mean number of insertions in landmark guided midline group was higher (1.90±0.02) as compared to landmark guided paramedian group in our study (1.49±0.51) which can be attributed to the geriatric study population in their study.[40] Also, the midline technique of spinal anaesthesia performed by them is considered technically difficult than paramedian approach in elderly patients.[1,41]

In our study, the median number of needle redirections was 1(IQR 0-2) in group B and 2(IQR 1-3) in group B, which was statistically significant with p value 0.014. Our results are in contrast to the study conducted by Conroy et al where the median number of needle passes were [3(IOR 1-6)] with real time ultrasound.[3] This could be attributed to the fact that patients belonged to geriatric age group with mean age 66±11 as compared to mean age55.17±14.72 in group B of our study. In elderly population there occurs calcification of ligaments along with degenerative changes of spine and hypertrophy of the facet joints

which makes spinal anaesthesia more difficult leading to more redirections as compared to in younger population.[17,5]

Ravi et al in their observed that the median number of needle passes were more in real time ultrasound group [4(IQR 3-4] as compared to in our study [1(IQR 0-2)].This can be attributed to the fact that number of needle passes were being recorded by an independent observer in their study whereas it was self-reported in our study.[23] It has been observed that the number of self-reported redirections are always counted less than the actual number of redirections.[23,42]

In our study, the mean number of total needle attempts (needle insertion plus needle redirection) were lower in group B (2.23±1.21) than in group A (3.43±1.54), which was statistically significant with p value 0.001.

Raghu et al in their study noted that mean total number of attempts were 3.90(±0.51) in RUS group.[4] This difference could be ascribed to the expertise of the operators as performance of RUS spinal anaesthesia has a long learning curve and success rate is definitely affected by the experience of the performer.[4]

We observed in our study that in group A, 22.9% patients required needle insertions attempt at a different intrathecal space compared to 2.9% patients in group B. In a study conducted by Kampitak et al, 19.4% patients in the landmark group required needle insertions at multiple intrathecal spaces which is comparable with our study.[17]

The success rate for achieving spinal anaesthesia were similar in both the groups in our study. (100% in group B and 97% in group A). This is comparable with the studies done by Ravi et al and Conroy et al who observed success rates of 98% and 97% for spinal anaesthesia with real time ultrasound respectively.[3, 23]

In our study, we found that the median time taken for identification of the best intervertebral space was more in real time ultrasound group [2.5 (IQR 2.1-3) minutes] as compared to landmark group [0.5 (IQR 0.33-0.66) minutes]. Our results are in contrast with study done by P.H Conroy who in their observational study on real time ultrasound guided spinal anaesthesia, found median time for identification of space was

3.9minutes.[3] The lesser time for identification of the best intervertebral space in our study is because we did not include scouting time in our patient population.

In our study, mean time taken to identify the anatomical landmarks (assessment time) was longer in group B [155.83 (±37.59)sec] than in group A [29.97(±9.72)sec] which was statistically significant with p value 0.001. In a study done by Bhardwaj D et al the mean time taken for identification of landmarks in real time ultrasound group was 36.14 ± 3.02 seconds.[22] These findings are in contrast to our study findings. This could be attributed to the fact that patients had lower BMI(23.85 ± 3.03) in their study as compared to our study (BMI 34.91 ± 3.90) .In patients with higher BMI, structures are less distinct on ultrasonography because of the attenuation that occurs as ultrasound beams travel a greater distance through soft tissue. Further, in irregularly shaped adipose layers, a phase aberration effect is caused by the varying speed of sound which could have further contributed to lower success rate with ultrasound in our study.[5,43]

In present study, mean time taken from insertion of needle to acquisition of CSF (procedure time) was lesser in group B (0.67±0.21minutes) as compared to in group A (1.42±0.46 minutes). Our results are in accordance with study done by Chong S.E et al who observed that the mean time for a successful dural puncture was lesser in real time ultrasound group (0.69±1.01min) than in landmark group(1.60±1.19 min).[11] Whereas in the study conducted by Elsharkawy et al, the real time ultrasound group had a longer procedure time (256 seconds) than landmark group (117 seconds).[15] This could be attributed to the fact that the majority patients were elderly with mean age of 70±10 in their study, as compared to mean age of 55.17±14.72 in our study.

The meantotal procedure time was longer in group B (3.29±0.80 min) as compared to in group A (1.88±0.65 min) which was statistically significant with p value 0.001. In a study done by Conroy et al, the mean time taken for real time scanning of spaces until completion of

the intrathecal injection was 3±3.5 minutes which is similar to the mean total procedure time in group B of our study.[3]

Higher peri-procedural pain score(>4) and discomfort score(>2) were noted in34.3% and 34.3% patients in group A as compared to 22.9% and 11.4% patients in group B respectively. This is in accordance with the lesser number of needle insertions and redirections and also lower procedure time seen in group B as compared to group A in our study. So, lesser number of needle insertions and redirections along with decreased procedure time could have contributed to lower peri-procedural pain and discomfort with real time ultrasound guided technique. In a study conducted by Kumar anil et al, all patients in landmark group had low peri-procedural pain score (between 1-4) as compared to 34.3% patients, who had a pain score >4 in group A in our study.[28] This could be attributed to the fact that the study population was younger (mean age 38.96±14.59) with low BMI (mean25.32±2.96), so they might not have encountered anatomical challenges in their study which were seen in our study with obese patients.[28]

Only one patient in real time ultrasound guided group and three patients in landmark group reported traumatic bloody tap. Failure of dural puncture occurred in one patient in landmark group, however the procedure was completed by converting the technique to real time ultrasound guided method.

Limitations

There were few limitations in our study worth mentioning. Although, our study was on difficult spinal anatomy too, but we did not get patients with abnormal spine deformities like scoliosis, kyphosis and none of our patients had history of previous spine procedure both of which are typical conditions that would make spinal anaesthesia more challenging to administer. This was probably due to the ongoing covid pandemic where the number of routine surgeries being carried out were limited. Secondly, the number of needle redirections were self reported in our study but self reporting is generally lesser than the

actual number of needle redirections. So an independent observer to note down the number of needle redirections would have been better.

Conclusion:

A real time ultrasound guided paramedian approach for spinal anaesthesia in obese patients significantly decreases the number of needle insertion attempts and redirections leading to decreased peri-procedural discomfort to the patient. Even though with the use of real time ultrasound, assessment time increases when compared to landmark technique but the procedure time decreases.

SUMMARY AND CONCLUSION

1. This study was conducted in a prospective randomized manner in Department of Anesthesiology, Dayanand Medical College and Hospital on a total of 70 patients aged > 18 years, to ASA grade I, II & III with difficult spine anatomy, scheduled for elective surgeries under spinal anaesthesia.
2. A total of 70 eligible patients were randomly allocated to either of two study groups of 35 patients each by computer generated randomization codes sealed in sequentially numbered envelopes.

a) **Group A -**Patients received spinal anaesthesia by conventional surface landmark- guided paramedian technique.

b) **Group B -**Patient received spinal anaesthesia by an ultrasound guided paramedian technique

3. Primary outcome of our study was to compare the first needle insertion attempts required for successful acquisition of CSF, between both the techniques.
4. The Real time ultrasound guided paramedian group had a higher success rate (40.0%) of dural puncture in first needle insertion attempt as compared to the conventional surface landmark guided paramedian technique group (11.4%) and this was statistically significant with p value 0.006.
5. The secondary outcomes of the study were the total number of attempts, the total procedure time required for successful dural puncture, peri-procedural pain and discomfort scores and complications if any
6. In our study, the mean number of needle insertion was lower in group B 1.03 (±0.17) as compared to in group A 1.49 (±0.51) which was statistically significant with p value 0.001.
7. The mean number of total attempts (needle insertion plus needle redirection) was lower in group B 2.23(±1.21) than in group A 3.43(±1.54), which was statistically significant with p value 0.001

8. The success rate of achieving spinal anaesthesia in both groups was similar (RUS 100%, landmark 97 %).
9. The mean total procedure time (sum of assessment time and procedure time) was longer in group B 3.29±0.80 minutes as compared to in group A 1.88±0.65 minutes which was statistically significant with p value 0.001. Although the assessment time was longer but the procedural time was significantly lesser in group B (0.67±0.21 minutes) as compared to group A (1.42±0.46 minutes).
10. In group A, 34.3% patients had a peri-procedural pain score of >4 as compared to 22.9% patients in group B which was statistically insignificant.
11. Peri-procedural discomfort score of >2 was noted in 34.3% patients in group A and 11.4% patients in group B which was statistically significant.
12. Only one patient in real time ultrasound guided group and three patients in landmark group reported traumatic bloody tap.
13. Failure of dural puncture occurred in one patient in landmark group and the procedure was completed by converting the technique to real time ultrasound guided method.
14. It was concluded that a real time ultrasound guided paramedian technique for spinal anaesthesia in patients with difficult spine anatomy significantly decreased the number of needle insertions and redirections. Even though with the use of real time ultrasound, assessment time increased but the procedure time decreased.

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S. NO	MRD	NAME	GROUP	AGE (YEARS)	SEX	HEIGHT (CM)	WEIGHT (KG)	BMI (KG/M^2)	ASA GRADE	H/O PREVIOUS SPINAL SURGERY IN THE PAST	LUMBAR SPINE DEFORMITY	KYPHOSIS	SCOLIOSIS	LORDOSIS	SPINOUS PROCESSES	HEMOGLOBIN (GM/DL)	TLC (10 ^3/ul)	PLATELET COUNT (10^3/ul)	PTI	INR	PRE PROCEDURE VITALS	HR (BPM)
3	1053242	SK	A	44	FEMALE	149	96	43.2	3	NO	ABSENT	-	-	-	IMPALPABLE	10.5	7.3	180	-	0.93	-	106
4	1056460	SS	B	50	MALE	175	125	40.82	2	NO	ABSENT	-	-	-	IMPALPABLE	9.8	7	253	-	0.98	-	90
5	1124639	KJS	A	59	MALE	157	76	30.83	3	NO	ABSENT	-	-	-	POORLY PALPABLE	7.8	9.7	272	14.2	1.3	-	80
6	328760	KL	B	66	MALE	162	86	32.77	3	NO	ABSENT	-	-	-	POORLY PALPABLE	10	8.5	175	10.2	0.94	-	96
7	55543	BS	B	47	MALE	172	95	32.11	3	NO	ABSENT	-	-	-	POORLY PALPABLE	9.4	5.2	252	13.6	1.24	-	82
8	5387	MP	B	46	MALE	177	100	31.92	3	NO	ABSENT	-	-	-	IMPALPABLE	14.1	7.3	202	11.1	1.02	-	68
9	640305	NPS	B	66	MALE	170	87	30.10	2	NO	ABSENT	-	-	-	POORLY PALPABLE	8.2	8.7	439	14.3	1.31	-	104
11	1127191	BS	B	42	MALE	165	95	34.89	2	NO	ABSENT	-	-	-	POORLY PALPABLE	14.7	16	221	-	1.11	-	64
12	1015320	RT	A	46	MALE	175	104	33.96	3	NO	ABSENT	-	-	-	POORLY PALPABLE	8.6	5.7	120	-	1.38	-	90
13	718008	GK	A	70	FEMALE	147	70	32.39	1	NO	ABSENT	-	-	-	POORLY PALPABLE	9.8	10.5	222	-	1.03	-	84
14	1032914	RR	B	71	FEMALE	152	72	31.16	2	NO	ABSENT	-	-	-	POORLY PALPABLE	10.1	9.6	251	-	1.01	-	70
15	1133402	DS	A	63	MALE	172	93	31.44	3	NO	ABSENT	-	-	-	POORLY PALPABLE	11	8.9	217	11.4	1.05	-	86
16	1132679	SD	A	63	FEMALE	152	72	31.16	1	NO	ABSENT	-	-	-	POORLY PALPABLE	12	5.8	201	-	1.07	-	110
17	1134885	MK	B	56	FEMALE	152	78	33.76	2	NO	ABSENT	-	-	-	POORLY PALPABLE	10.6	10.4	227	-	1.61	-	98
18	1137032	PS	B	41	MALE	170	92	31.83	2	NO	ABSENT	-	-	-	IMPALPABLE	11	5.8	268	111	1.09	-	76
19	1148678	KS	A	45	MALE	175	92	30.04	3	NO	ABSENT	-	-	-	IMPALPABLE	12.5	7	292	13.5	1.2	-	72
20	1159595	BS	B	29	MALE	167	93	33.35	1	NO	ABSENT	-	-	-	POORLY PALPABLE	15.3	5.1	150	10.5	0.9	-	56
21	1162797	SS	B	60	MALE	167	116	41.59	3	NO	ABSENT	-	-	-	IMPALPABLE	11.7	7.6	150	-	1.05	-	80
22	1176647	BS	B	77	MALE	182	107	32.30	2	NO	ABSENT	-	-	-	IMPALPABLE	14.8	6.8	150	14.7	1.19	-	78
23	1185411	KR	B	67	FEMALE	162	90	34.29	2	NO	ABSENT	-	-	-	IMPALPABLE	8.5	6.9	240	-	1.15	-	90
24	952689	RG	B	57	MALE	170	110	38.06	2	NO	ABSENT	-	-	-	IMPALPABLE	13.9	5.9	165	11.9	1.09	-	80
25	993815	VJ	A	59	MALE	165	90	33.06	3	NO	ABSENT	-	-	-	POORLY PALPABLE	15.3	16.4	264	-	1.21	-	90
26	1174535	ML	A	65	MALE	170	100	34.60	1	NO	ABSENT	-	-	-	IMPALPABLE	11	10.7	266	-	1	-	91
27	1226605	SS	A	27	MALE	172	103	34.82	2	NO	ABSENT	-	-	-	IMPALPABLE	15.9	8.9	204	-	1	-	110
28	1228839	DB	B	49	MALE	170	89	30.80	3	NO	ABSENT	-	-	-	POORLY PALPABLE	13.3	8.3	263	-	1	-	89
29	1229183	MV	B	68	MALE	165	90	33.06	3	NO	ABSENT	-	-	-	IMPALPABLE	13.5	6.5	160	-	1.09	-	80
30	1216491	G	A	55	MALE	170	90	31.14	2	NO	ABSENT	-	-	-	IMPALPABLE	9.1	9.4	524	-	1.04	-	89
31	1228876	AS	B	69	MALE	170	98	33.91	3	NO	ABSENT	-	-	-	IMPALPABLE	8.1	7.8	303	13.2	1.21	-	78
32	904008	TK	A	30	FEMALE	157	98	39.76	2	NO	ABSENT	-	-	-	IMPALPABLE	10.7	13	328	-	0.92	-	89
33	1133029	GS	A	34	MALE	170	95	32.87	1	NO	ABSENT	-	-	-	POORLY PALPABLE	9.3	7.5	162	11.7	1.07	-	104
34	1235582	DJ	A	32	MALE	170	98	33.91	2	NO	ABSENT	-	-	-	IMPALPABLE	14.3	10.8	369	11.4	1.04	-	70
35	1234634	SK	B	62	FEMALE	165	111	40.77	3	NO	ABSENT	-	-	-	IMPALPABLE	11.7	10.8	293	11.3	0.83	-	62
36	1236579	SK	B	47	MALE	167	120	43.03	3	NO	ABSENT	-	-	-	IMPALPABLE	12.1	16.1	199	15	1.37	-	110
37	148220	PG	B	82	FEMALE	160	78	30.47	3	NO	ABSENT	-	-	-	POORLY PALPABLE	11.1	10.5	176	15.3	1.41	-	110
38	1237162	SS	A	45	MALE	172	89	30.08	2	NO	ABSENT	-	-	-	IMPALPABLE	11.7	6.2	307	12.8	1.17	-	76
39	1243099	BS	B	65	MALE	170	103	35.64	3	NO	ABSENT	-	-	-	IMPALPABLE	7.7	11.7	214	-	0.9	-	78
40	1234223	MK	B	19	MALE	170	90	31.14	2	NO	ABSENT	-	-	-	POORLY PALPABLE	10	5.2	409	16.1	1.47	-	92
41	1244442	RS	B	67	MALE	170	88	30.45	3	NO	ABSENT	-	-	-	POORLY PALPABLE	6.4	11.3	179	-	1.4	-	95
42	103526	DM	B	23	FEMALE	160	89	34.77	2	NO	ABSENT	-	-	-	POORLY PALPABLE	11.2	8.2	261	-	1.08	-	87
43	1143908	SK	B	55	FEMALE	152	75	32.46	3	NO	ABSENT	-	-	-	POORLY PALPABLE	10.8	6.3	260	12	1.03	-	78
44	1163057	SK	B	70	FEMALE	167	98	35.14	3	NO	ABSENT	-	-	-	IMPALPABLE	9.9	12.9	506	-	1.33	-	76
45	1244024	ND	A	62	FEMALE	157	80	32.46	3	NO	ABSENT	-	-	-	IMPALPABLE	9.3	11.4	348	14.7	1.34	-	86

S. NO	MRD	SBP (mmHg)	DBP (mmHg)	SPO2 % RA	RR	POST PROCEDURE VITALS	HR	BP	-	SPO2	RR (PER MINT)	ASSESMENT TIME (SECONDS)	PROCEDURE TIME (SECONDS)	TOTAL PROCEDURE TIME (SECONDS)	NUMBER OF NEEDLE INSERTION	NUMBER OF NEEDLE REDIRECTION	TOTAL ATTEMPTS	SPACE OF SUCCESSFUL BLOCK	PARASPINAL SPACE	NO CHANGE IN LEVEL OF PARASPINAL CHANGE	NO CHANGE IN LEVEL OF PARASPINAL SPACE ON 1ST NEEDLE INSERTION ATTEMPT	NO CHANGE IN LEVEL OF PARASPINAL SPACE ON 2ND NEEDLE INSERTION ATTEMPT
3	1053242	120	80	100	16	-	104	110	70	98	16	40	150	190	2	4	6	L3-L4	-	-	-	-
4	1056460	130	70	98	16	-	94	120	70	98	16	180	40	220	1	3	4	L3-L4	-	YES	YES	-
5	1124639	160	100	100	16	-	70	153	99	100	16	20	60	80	1	0	1	L4-L5	-	YES	YES	-
6	328760	162	91	98	18	-	90	112	70	99	16	128	42	170	1	0	1	L3-L4	-	YES	YES	-
7	55543	120	70	97	16	-	82	120	70	97	15	145	40	185	1	1	2	L4-L5	-	YES	YES	-
8	5387	123	73	96	18	-	68	113	63	97	17	150	20	170	1	0	1	L3-L4	-	YES	YES	-
9	640305	110	70	96	15	-	101	138	85	98	15	60	20	80	1	0	1	L3-L4	-	YES	YES	-
11	1127191	140	80	98	15	-	63	125	71	96	16	125	18	143	1	0	1	L3-L4	-	YES	YES	-
12	1015320	140	80	100	16	-	80	120	70	100	15	40	70	110	2	1	3	L3-L4	-	YES	-	YES
13	718008	140	70	98	18	-	77	149	61	98	16	20	50	70	1	0	1	L3-L4	-	YES	YES	-
14	1032914	140	70	97	16	-	77	120	70	97	16	120	30	150	1	0	1	L3-L4	-	YES	YES	-
15	1133402	110	117	96	16	-	67	154	104	98	16	20	50	70	1	0	1	L3-L4	-	YES	YES	-
16	1132679	120	70	96	16	-	98	110	65	97	16	25	40	65	1	0	1	L3-L4	-	YES	YES	-
17	1134885	120	70	96	16	-	92	110	60	97	18	170	40	210	1	1	2	L3-L4	-	YES	YES	-
18	1137032	130	80	96	18	-	72	110	60	96	18	145	30	175	1	0	1	L3-L4	-	YES	YES	-
19	1148678	140	80	97	16	-	81	135	83	98	16	20	60	80	1	1	2	L3-L4	-	YES	YES	-
20	1159595	130	80	97	20	-	58	121	71	99	20	145	40	185	1	1	2	L3-L4	-	YES	YES	-
21	1162797	140	90	96	20	-	75	136	87	96	20	210	65	275	1	3	4	L4-L5	-	YES	YES	-
22	1176647	180	90	94	16	-	77	175	83	100	16	195	60	255	1	2	3	L3-L4	-	YES	YES	-
23	1185411	170	90	99	16	-	84	160	80	99	16	177	43	220	1	1	2	L3-L4	-	YES	YES	-
24	952689	110	70	99	16	-	78	90	60	98	18	150	50	200	1	2	3	L3-L4	-	YES	YES	-
25	993815	130	90	99	16	-	80	110	70	98	16	30	80	110	2	1	3	L3-L4	-	-	-	-
26	1174535	130	80	98	16	-	90	110	70	97	16	35	90	125	2	2	4	L4-L5	-	YES	-	YES
27	1226605	140	60	96	16	-	100	120	70	94	16	40	90	130	2	2	4	L4-L5	-	YES	-	YES
28	1228839	150	80	90	16	-	74	130	76	100	16	130	20	150	1	0	1	L4-L5	-	YES	YES	-
29	1229183	170	100	100	18	-	70	160	90	100	16	180	50	230	1	0	1	L3-L4	-	YES	YES	-
30	1216491	110	70	97	16	-	77	90	60	98	16	35	75	110	1	2	3	L3-L4	-	YES	YES	-
31	1228876	130	70	98	18	-	68	120	70	97	16	180	50	230	1	1	2	L3-L4	-	YES	YES	-
32	904008	180	95	98	16	-	88	158	89	98	16	50	130	180	2	4	6	L4-L5	-	-	-	-
33	1133029	145	85	99	16	-	100	130	70	99	18	26	73	99	1	3	4	L3-L4	-	YES	YES	-
34	1235582	110	60	100	18	-	68	100	60	100	16	30	85	115	2	2	4	L3-L4	-	YES	-	YES
35	1234634	110	70	99	16	-	60	100	70	98	16	200	60	260	1	3	4	L4-L5	-	YES	YES	-
36	1236579	130	80	95	18	-	108	110	60	96	16	220	60	280	2	2	4	L4-L5	-	-	-	-
37	148220	116	70	96	16	-	105	106	70	98	18	150	40	190	1	0	1	L3-L4	-	YES	YES	-
38	1237162	110	70	97	16	-	84	120	70	96	16	47	93	140	1	1	2	L3-L4	-	YES	YES	-
39	1243099	130	70	98	16	-	72	120	60	98	16	130	50	180	1	2	3	L4-L5	-	YES	YES	-
40	1234223	120	70	97	16	-	89	110	60	97	18	140	50	190	1	0	1	L3-L4	-	YES	YES	-
41	1244442	140	90	100	16	-	88	130	70	98	16	110	30	140	1	0	1	L3-L4	-	YES	YES	-
42	103526	110	70	98	16	-	80	90	60	98	16	164	55	219	1	2	3	L3-L4	-	YES	YES	-
43	1143908	110	70	98	16	-	80	100	60	98	18	120	34	154	1	1	2	L3-L4	-	YES	YES	-
44	1163057	110	80	98	16	-	74	97	50	100	16	100	40	140	1	2	3	L3-L4	-	YES	YES	-
45	1244024	140	70	96	16	-	74	110	60	98	16	20	70	90	1	1	2	L3-L4	-	YES	YES	-

S. NO	MRD	CHANGE IN LEVEL OF PARASPINAL SPACE	L2-L3 TO L3-L4	L3-L4 TO L4-L5	L4-L5 TO L2-L3	L4-L5 TO L3-L4	PERI-PROCEDURAL PAIN SCORE (0 - 10)	PERIPROCEDURAL DISCOMFORT SCORE (0 - 5)	BEST PALPABLE SPACE	L2-L3	L3-L4	L4-L5	NOT APPLICABLE	GRADING OF PALPATED LANDMARKS	PALPABLE	POORLY PALPABLE	UNPALPABLE	NOT APPLICABLE
3	1053242	YES	-	-	-	YES	8	4	-	-	YES	-	-	-	-	-	YES	-
4	1056460	-	-	-	-	-	4	2	-	-	-	-	N/A	-	-	-	-	N/A
5	1124639	-	-	-	-	-	4	3	-	-	-	YES	-	-	-	YES	-	-
6	328760	-	-	-	-	-	2	1	-	-	-	-	N/A	-	-	-	-	N/A
7	55543	-	-	-	-	-	2	1	-	-	-	-	N/A	-	-	-	-	N/A
8	5387	-	-	-	-	-	2	0	-	-	-	-	N/A	-	-	-	-	N/A
9	640305	-	-	-	-	-	6	4	-	-	-	-	N/A	-	-	-	-	N/A
11	1127191	-	-	-	-	-	2	0	-	-	-	-	N/A	-	-	-	-	N/A
12	1015320	-	-	-	-	-	7	3	-	-	YES	-	-	-	-	YES	-	-
13	718008	-	-	-	-	-	3	2	-	-	YES	-	-	-	-	YES	-	-
14	1032914	-	-	-	-	-	2	0	-	-	-	-	N/A	-	-	-	-	N/A
15	1133402	-	-	-	-	-	3	3	-	-	YES	-	-	-	-	YES	-	-
16	1132679	-	-	-	-	-	4	1	-	-	YES	-	-	-	-	YES	-	-
17	1134885	-	-	-	-	-	3	2	-	-	-	-	N/A	-	-	-	-	N/A
18	1137032	-	-	-	-	-	3	1	-	-	-	-	N/A	-	-	-	-	N/A
19	1148678	-	-	-	-	-	4	2	-	-	YES	-	-	-	-	-	YES	-
20	1159595	-	-	-	-	-	0	0	-	-	-	-	N/A	-	-	-	-	N/A
21	1162797	-	-	-	-	-	3	0	-	-	-	-	N/A	-	-	-	-	N/A
22	1176647	-	-	-	-	-	4	2	-	-	-	-	N/A	-	-	-	-	N/A
23	1185411	-	-	-	-	-	3	2	-	-	-	-	N/A	-	-	-	-	N/A
24	952689	-	-	-	-	-	2	0	-	-	-	-	N/A	-	-	-	-	N/A
25	993815	YES	-	-	-	YES	6	3	-	-	YES	-	-	-	-	-	YES	-
26	1174535	-	-	-	-	-	5	3	-	-	-	YES	-	-	-	-	YES	-
27	1226605	-	-	-	-	-	2	0	-	-	-	YES	-	-	-	-	YES	-
28	1228839	-	-	-	-	-	3	1	-	-	-	-	N/A	-	-	-	-	N/A
29	1229183	-	-	-	-	-	2	0	-	-	-	-	N/A	-	-	-	-	N/A
30	1216491	-	-	-	-	-	5	2	-	-	YES	-	-	-	-	-	YES	-
31	1228876	-	-	-	-	-	5	1	-	-	-	-	N/A	-	-	-	-	N/A
32	904008	YES	-	YES	-	-	8	3	-	-	-	YES	-	-	-	-	YES	-
33	1133029	-	-	-	-	-	4	2	-	-	YES	-	-	-	-	YES	-	-
34	1235582	-	-	-	-	-	3	1	-	-	YES	-	-	-	-	-	YES	-
35	1234634	-	-	-	-	-	4	2	-	-	-	-	N/A	-	-	-	-	N/A
36	1236579	YES	-	YES	-	-	4	2	-	-	-	-	N/A	-	-	-	-	N/A
37	148220	-	-	-	-	-	3	1	-	-	-	-	N/A	-	-	-	-	N/A
38	1237162	-	-	-	-	-	3	0	-	-	YES	-	-	-	-	-	YES	-
39	1243099	-	-	-	-	-	6	1	-	-	-	-	N/A	-	-	-	-	N/A
40	1234223	-	-	-	-	-	3	2	-	-	-	-	N/A	-	-	-	-	N/A
41	1244442	-	-	-	-	-	5	0	-	-	-	-	N/A	-	-	-	-	N/A
42	103526	-	-	-	-	-	5	4	-	-	-	-	N/A	-	-	-	-	N/A
43	1143908	-	-	-	-	-	3	0	-	-	-	-	N/A	-	-	-	-	N/A
44	1163057	-	-	-	-	-	5	1	-	-	-	-	N/A	-	-	-	-	N/A
45	1244024	-	-	-	-	-	1	0	-	-	YES	-	-	-	-	-	YES	-

S. NO	MRD	BEST QUALITY OF SPACE IN ULTRASOUND SCAN	L2-L3	L3-L4	L4-L5	NOT APPLICABLE	VIEW OF ULTRASOUND GUIDED TECHNIQUE	GOOD	INTERMEDIATE	POOR	NOT APPLICABLE	COMPLICATIONS	BLOODY TAP	PARAESTHESIA	FAILURE OF TECHNIQUE	CONVERSION OF TECHNIQUE	LANDMARK GUIDED TO ULTASOUND GUIDED TECHNIQUE	ULTRASOUND GUIDED TO LANDMARK GUIDED TECHNIQUE	CONVERTED TO GENERAL ANAESTHESIA
3	1053242	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
4	1056460	-	-	YES	-	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
5	1124639	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
6	328760	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
7	55543	-	-	-	YES	-	-	-	YES	-	-	-	NO	NO	NO	-	NO	NO	NO
8	5387	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
9	640305	-	-	YES	-	-	-	YES	-	-	-	-	YES	NO	NO	-	NO	NO	NO
11	1127191	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
12	1015320	-	-	-	-	N/A	-	-	-	-	N/A	-	YES	NO	NO	-	NO	NO	NO
13	718008	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
14	1032914	-	-	YES	-	-	-	yes	-	-	-	-	NO	NO	NO	-	NO	NO	NO
15	1133402	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
16	1132679	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
17	1134885	-	-	YES	-	-	-	-	YES	-	-	-	NO	NO	NO	-	NO	NO	NO
18	1137032	-	-	YES	-	-	-	-	YES	-	-	-	NO	NO	NO	-	NO	NO	NO
19	1148678	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
20	1159595	-	-	YES	-	-	-	-	YES	-	-	-	NO	NO	NO	-	NO	NO	NO
21	1162797	-	-	-	YES	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
22	1176647	-	-	YES	-	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
23	1185411	-	-	YES	-	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
24	952689	-	-	YES	-	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
25	993815	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
26	1174535	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
27	1226605	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
28	1228839	-	-	-	YES	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
29	1229183	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
30	1216491	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
31	1228876	-	-	YES	-	-	-	-	YES	-	-	-	NO	NO	NO	-	NO	NO	NO
32	904008	-	-	-	-	N/A	-	-	-	-	N/A	-	YES	NO	NO	-	NO	NO	NO
33	1133029	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
34	1235582	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
35	1234634	-	-	-	YES	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
36	1236579	-	-	-	YES	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
37	148220	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
38	1237162	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
39	1243099	-	-	-	YES	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
40	1234223	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
41	1244442	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
42	103526	-	-	YES	-	-	-	-	YES	-	-	-	NO	NO	NO	-	NO	NO	NO
43	1143908	-	-	YES	-	-	-	-	YES	-	-	-	NO	NO	NO	-	NO	NO	NO
44	1163057	-	-	YES	-	-	-	-	YES	-	-	-	NO	NO	NO	-	NO	NO	NO
45	1244024	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO

S. NO	MRD	NAME	GROUP	AGE (YEARS)	SEX	HEIGHT (CM)	WEIGHT (KG)	BMI (KG/M^2)	ASA GRADE	H/O PREVIOUS SPINAL SURGERY IN THE PAST	LUMBAR SPINE DEFORMITY	KYPHOSIS	SCOLIOSIS	LORDOSIS	SPINOUS PROCESSES	HEMOGLOBIN (GM/DL)	TLC (10 ^3/ul)	PLATELET COUNT (10^3/ul)	PTI	INR	PRE PROCEDURE VITALS	HR (BPM)
46	1250953	RK	A	53	MALE	167	95	34.06	3	NO	ABSENT	-	-	-	IMPALPABLE	9.1	13	202	12.9	1.18	-	88
47	1261529	MS	B	56	MALE	172	115	38.87	2	NO	ABSENT	-	-	-	IMPALPABLE	10.2	12.2	297	-	1.05	-	109
48	1256639	SS	A	49	MALE	165	100	36.73	3	NO	ABSENT	-	-	-	IMPALPABLE	9.7	12.6	593	-	1.46	-	90
49	1293038	GS	A	51	MALE	172	100	33.80	3	NO	ABSENT	-	-	-	IMPALPABLE	11.1	10.6	242	12	1.1	-	80
50	1249868	SPK	B	67	FEMALE	170	120	41.52	3	NO	ABSENT	-	-	-	IMPALPABLE	9.6	6.2	117	14.3	1.31	-	62
51	1298410	ND	B	40	MALE	175	122	39.84	1	NO	ABSENT	-	-	-	IMPALPABLE	13	7.9	191	12.7	1.16	-	78
52	830887	KK	B	60	FEMALE	152	95	41.12	3	NO	ABSENT	-	-	-	IMPALPABLE	13.7	5.7	260	-	0.81	-	84
53	1295847	JS	B	58	MALE	177	100	31.92	2	NO	ABSENT	-	-	-	POORLY PALPABLE	12.5	9.1	257	-	0.96	-	89
54	321649	AN	B	42	MALE	170	88	30.45	1	NO	ABSENT	-	-	-	POORLY PALPABLE	13.2	10.3	269	12.2	1.12	-	84
55	1297059	MK	A	60	FEMALE	165	92	33.79	2	NO	ABSENT	-	-	-	POORLY PALPABLE	10.5	6.7	174	11.4	1.05	-	86
56	1307261	SS	A	65	MALE	170	95	32.87	3	NO	ABSENT	-	-	-	POORLY PALPABLE	13.1	8.5	179	-	1.03	-	104
58	980231	HP	A	30	MALE	185	132	38.57	3	NO	ABSENT	-	-	-	IMPALPABLE	14.2	9.2	236	11.2	1.03	-	78
59	1308356	SS	B	63	MALE	167	108	38.72	3	NO	ABSENT	-	-	-	IMPALPABLE	13.4	10.8	140	10.8	0.99	-	78
60	1311682	PK	B	37	FEMALE	157	85	34.48	2	NO	ABSENT	-	-	-	IMPALPABLE	11.2	11.47	150	11.5	1.05	-	106
61	807288	SCS	B	57	MALE	182	114	34.42	2	NO	ABSENT	-	-	-	IMPALPABLE	9.3	6.9	169	11.3	1.04	-	68
62	1310649	JG	A	60	MALE	172	100	33.80	3	NO	ABSENT	-	-	-	IMPALPABLE	10.6	21	160	15.5	1.42	-	99
63	1300285	JA	A	28	MALE	162	94	35.82	2	NO	ABSENT	-	-	-	IMPALPABLE	14.9	11.5	263	12	1.08	-	110
64	1231036	SP	A	55	MALE	187	135	38.61	2	NO	ABSENT	-	-	-	IMPALPABLE	11	11	278	10.2	1.1	-	74
65	306464	TS	A	17	MALE	157	83	33.67	1	NO	ABSENT	-	-	-	POORLY PALPABLE	12.2	7.8	291	11.4	1.05	-	107
66	1300692	I	A	66	MALE	152	72	31.16	2	NO	ABSENT	-	-	-	POORLY PALPABLE	11.6	6.8	270	12	1.1	-	81
67	1322375	HK	A	52	MALE	165	90	33.06	2	NO	ABSENT	-	-	-	IMPALPABLE	12.9	8.9	189	10.4	0.95	-	74
68	1325645	VJ	A	53	FEMALE	162	95	36.20	3	NO	ABSENT	-	-	-	IMPALPABLE	6.7	9.3	572	13.6	1.24	-	98
69	1324001	JK	A	75	FEMALE	165	104	38.20	3	NO	ABSENT	-	-	-	IMPALPABLE	13.3	18.1	110	12.9	1.18	-	84
70	1325992	LS	A	55	FEMALE	170	98	33.91	3	NO	ABSENT	-	-	-	IMPALPABLE	11.1	15	175	11.2	1.03	-	81
71	1326875	BK	A	57	FEMALE	162	90	34.29	2	NO	ABSENT	-	-	-	IMPALPABLE	12.9	10.1	212	10.9	1	-	78
72	363666	GS	A	36	MALE	190	113	31.30	2	NO	ABSENT	-	-	-	POORLY PALPABLE	14.1	7.1	189	11	1.01	-	80
73	1327664	GV	A	37	MALE	170	100	34.60	2	NO	ABSENT	-	-	-	POORLY PALPABLE	13.5	8.2	199	11.6	1.06	-	90
74	1344545	NM	A	45	FEMALE	152	105	45.45	3	NO	ABSENT	-	-	-	IMPALPABLE	12.1	7.1	204	-	-	-	80

S. NO	MRD	SBP (mmHg)	DBP (mmHg)	SPO2 % RA	RR	POST PROCEDURE VITALS	HR	BP	-	SPO2	RR (PER MINT)	ASSESMENT TIME (SECONDS)	PROCEDURE TIME (SECONDS)	TOTAL PROCEDURE TIME (SECONDS)	NUMBER OF NEEDLE INSERTION	NUMBER OF NEEDLE REDIRECTION	TOTAL ATTEMPTS	SPACE OF SUCCESSFUL BLOCK	PARASPINAL SPACE	NO CHANGE IN LEVEL OF PARASPINAL CHANGE	NO CHANGE IN LEVEL OF PARASPINAL SPACE ON 1ST NEEDLE INSERTION ATTEMPT	NO CHANGE IN LEVEL OF PARASPINAL SPACE ON 2ND NEEDLE INSERTION ATTEMPT
46	1250953	130	80	94	19	-	82	110	70	95	16	25	85	110	1	3	4	L3-L4	-	YES	YES	-
47	1261529	148	92	99	16	-	98	127	75	100	16	190	50	240	1	3	4	L3-L4	-	YES	YES	-
48	1256639	110	70	100	16	-	91	112	78	100	16	30	90	120	2	3	5	L3-L4	-	YES	-	YES
49	1293038	140	70	98	16	-	88	120	70	97	18	25	90	115	2	1	3	L3-L4	-	YES	-	YES
50	1249868	130	80	94	20	-	70	110	70	92	20	225	60	285	1	3	4	L4-L5	-	YES	YES	-
51	1298410	130	80	97	20	-	72	110	70	97	18	150	40	190	1	3	4	L3-L4	-	YES	YES	-
52	830887	160	90	96	18	-	107	149	88	94	16	165	35	200	1	3	4	L4-L5	-	YES	YES	-
53	1295847	156	104	96	16	-	87	148	92	98	16	160	30	190	1	0	1	L3-L4	-	YES	YES	-
54	321649	125	72	97	16	-	74	110	60	97	18	150	30	180	1	0	1	L3-L4	-	YES	YES	-
55	1297059	110	80	98	16	-	80	100	60	96	16	20	80	100	1	1	2	L3-L4	-	YES	YES	-
56	1307261	150	70	94	18	-	103	128	74	96	20	14	60	1	1	1	2	L3-L4	-	YES	YES	-
58	980231	170	110	98	18	-	79	166	102	98	20	30	110	140	2	3	5	L4-L5	-	-	-	-
59	1308356	144	91	94	20	-	93	143	91	94	20	140	45	185	1	2	3	L3-L4	-	YES	YES	-
60	1311682	130	90	97	18	-	108	120	87	98	16	115	25	140	1	0	1	L3-L4	-	YES	YES	-
61	807288	180	90	96	16	-	54	130	60	97	16	235	60	295	1	1	2	L4-L5	-	YES	YES	-
62	1310649	90	60	98	20	-	100	100	60	97	20	20	50	70	1	2	3	L3-L4	-	YES	YES	-
63	1300285	110	70	98	16	-	108	100	60	97	18	24	86	110	2	3	5	L2 -L3	-	-	-	-
64	1231036	140	90	98	18	-	64	120	60	97	20	35	120	155	2	4	6	L4-L5	-	-	-	-
65	306464	110	90	98	16	-	108	100	60	97	20	40	75	115	1	2	3	L3-L4	-	YES	YES	-
66	1300692	120	80	98	18	-	88	110	60	97	20	38	70	108	1	1	2	L4-L5	-	YES	YES	-
67	1322375	160	90	94	16	-	70	140	80	95	18	20	130	150	2	2	4	L4-L5	-	YES	-	YES
68	1325645	120	70	97	16	-	88	110	60	98	18	20	80	100	2	3	5	L3-L4	-	YES	-	YES
69	1324001	130	80	95	16	-	92	108	64	97	18	40	135	175	2	3	5	L3-L4	-	-	-	-
70	1325992	170	90	92	20	-	78	150	70	93	20	40	60	100	1	2	3	L4-L5	-	YES	YES	-
71	1326875	110	70	98	16	-	82	100	60	97	18	20	80	100	2	2	4	L3-L4	-	YES	YES	-
72	363666	130	70	98	16	-	85	110	60	98	18	30	70	100	1	1	2	L3-L4	-	YES	YES	-
73	1327664	120	80	98	16	-	94	110	70	98	18	30	80	110	1	3	4	L3-L4	-	YES	YES	-
74	1344545	120	70	98	16	-	88	110	60	97	16	50	150	200	2	4	6	L4-L5	-	-	-	-

S. NO	MRD	CHANGE IN LEVEL OF PARASPINAL SPACE	L2-L3 TO L3-L4	L3-L4 TO L4-L5	L4-L5 TO L2-L3	L4-L5 TO L3-L4	PERI-PROCEDURAL PAIN SCORE (0 - 10)	PERIPROCEDURAL DISCOMFORT SCORE (0 - 5)	BEST PALPABLE SPACE	L2-L3	L3-L4	L4-L5	NOT APPLICABLE	GRADING OF PALPATED LANDMARKS	PALPABLE	POORLY PALPABLE	UNPALPABLE	NOT APPLICABLE
46	1250953	-	-	-	-	-	3	0	-	-	YES	-	-	-	-	-	YES	-
47	1261529	-	-	-	-	-	4	2	-	-	-	-	N/A	-	-	-	-	N/A
48	1256639	-	-	-	-	-	4	0	-	-	YES	-	-	-	-	-	YES	-
49	1293038	-	-	-	-	-	4	1	-	-	YES	-	-	-	-	-	YES	-
50	1249868	-	-	-	-	-	5	4	-	-	-	-	N/A	-	-	-	-	N/A
51	1298410	-	-	-	-	-	3	2	-	-	-	-	N/A	-	-	-	-	N/A
52	830887	-	-	-	-	-	5	5	-	-	-	-	N/A	-	-	-	-	N/A
53	1295847	-	-	-	-	-	2	1	-	-	-	-	N/A	-	-	-	-	N/A
54	321649	-	-	-	-	-	2	0	-	-	-	-	N/A	-	-	-	-	N/A
55	1297059	-	-	-	-	-	3	0	-	-	YES	-	-	-	-	YES	-	-
56	1307261	-	-	-	-	-	1	0	-	-	YES	-	-	-	-	YES	-	-
58	980231	YES	-	YES	-	-	3	1	-	-	-	YES	-	-	-	-	YES	-
59	1308356	-	-	-	-	-	2	0	-	-	-	-	N/A	-	-	-	-	N/A
60	1311682	-	-	-	-	-	2	2	-	-	-	-	N/A	-	-	-	-	N/A
61	807288	-	-	-	-	-	3	2	-	-	-	-	N/A	-	-	-	-	N/A
62	1310649	-	-	-	-	-	5	2	-	-	YES	-	-	-	-	-	YES	-
63	1300285	YES	-	-	YES	-	4	2	-	YES	-	-	-	-	-	-	YES	-
64	1231036	YES	-	YES	-	-	7	3	-	-	-	YES	-	-	-	-	YES	-
65	306464	-	-	-	-	-	4	3	-	-	YES	-	-	-	-	YES	-	-
66	1300692	-	-	-	-	-	3	0	-	-	-	YES	-	-	-	YES	-	-
67	1322375	-	-	-	-	-	7	3	-	-	-	YES	-	-	-	-	YES	-
68	1325645	-	-	-	-	-	5	2	-	-	YES	-	-	-	-	-	YES	-
69	1324001	YES	-	-	-	YES	8	4	-	-	-	YES	-	-	-	-	YES	-
70	1325992	-	-	-	-	-	4	1	-	-	-	YES	-	-	-	-	YES	-
71	1326875	-	-	-	-	-	4	2	-	-	YES	-	-	-	-	-	YES	-
72	363666	-	-	-	-	-	4	2	-	-	YES	-	-	-	-	YES	-	-
73	1327664	-	-	-	-	-	4	2	-	-	YES	-	-	-	-	YES	-	-
74	1344545	YES	-	YES	-	-	8	5	-	-	-	YES	-	-	-	-	YES	-

S. NO	MRD	BEST QUALITY OF SPACE IN ULTRASOUND SCAN	L2-L3	L3-L4	L4-L5	NOT APPLICABLE	VIEW OF ULTRASOUND GUIDED TECHNIQUE	GOOD	INTERMEDIATE	POOR	NOT APPLICABLE	COMPLICATIONS	BLOODY TAP	PARAESTHESIA	FAILURE OF TECHNIQUE	CONVERSION OF TECHNIQUE	LANDMARK GUIDED TO ULTASOUND GUIDED TECHNIQUE	ULTRASOUND GUIDED TO LANDMARK GUIDED TECHNIQUE	CONVERTED TO GENERAL ANAESTHESIA
46	1250953	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
47	1261529	-	-	YES	-	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
48	1256639	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
49	1293038	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
50	1249868	-	-	-	YES	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
51	1298410	-	-	YES	-	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
52	830887	-	-	-	YES	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
53	1295847	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
54	321649	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
55	1297059	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
56	1307261	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
58	980231	-	-	-	-	N/A	-	-	-	-	N/A	-	YES	NO	NO	-	NO	NO	NO
59	1308356	-	-	YES	-	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
60	1311682	-	-	YES	-	-	-	YES	-	-	-	-	NO	NO	NO	-	NO	NO	NO
61	807288	-	-	-	YES	-	-	-	-	YES	-	-	NO	NO	NO	-	NO	NO	NO
62	1310649	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
63	1300285	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
64	1231036	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
65	306464	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
66	1300692	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
67	1322375	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
68	1325645	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
69	1324001	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
70	1325992	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
71	1326875	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
72	363666	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
73	1327664	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	NO	-	NO	NO	NO
74	1344545	-	-	-	-	N/A	-	-	-	-	N/A	-	NO	NO	YES	-	YES	-	-

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Date 6/11/2022

The Principal,
DMC, Ludhiana.

Subject: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 29.10.2021 has approved the plan of thesis of **Anita**, a student of your college for **MD Anaesthesiology** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis

Comparison of real time ultrasound assisted versus conventional landmark technique for spinal anaesthesia in patients with difficult spine anatomy.

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The student has to submit the four copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

3. *If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.*
4. *The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov. of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.*

COMPARISON OF REAL TIME ULTRASOUND ASSISTED VERSUS CONVENTIONAL LANDMARK TECHNIQUE FOR SPINAL ANAESTHESIA IN PATIENTS WITH DIFFICULT SPINE ANATOMY

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

DOCTOR OF MEDICINE

In

ANAESTHESIOLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

MARCH 2021

DR ANITA

DEPARTMENT OF ANAESTHESIOLOGY
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA
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ABSTRACT OF PLAN OF THESIS

Title	COMPARISON OF REAL TIME ULTRASOUND ASSISTED VERSUS CONVENTIONAL LANDMARK TECHNIQUE FOR SPINAL ANAESTHESIA IN PATIENTS WITH DIFFICULT SPINE ANATOMY
For the degree of	M.D. Anaesthesia
Name of the candidate	Dr. Anita
Supervisor	Dr. Shikha Gupta, Professor, Department of Anaesthesia, DMCH, Ludhiana
Co-supervisor	Dr. Kamakshi Garg, Associate Professor, Department of Anaesthesia, DMCH, Ludhiana Dr. Tanveer Singh, Assistant Professor, Department of Anaesthesia, DMCH, Ludhiana
Institution	Dayanand Medical College and Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: Spinal anaesthesia with conventional landmark technique can be challenging in patients with anatomical alterations of the lumber spine, such as poorly palpable spinous processes, scoliosis or previous lumbar spine surgery. Reducing the technical difficulty of neuraxial blockade is desirable because multiple needle insertion attempts may increase the risk of complications. The use of real time ultrasound guidance might help in reducing these difficulties .

Aim of Study: To compare the rate of successful dural puncture on first needle insertion attempt between ultrasound assisted paramedian technique and conventional landmark guided paramedian technique in patients with difficult spine.

Materials & methods: Seventy patients belonging to ASA grade I-III, aged 18 years or more of either sex with difficult spine anatomy scheduled for elective surgeries under spinal anaesthesia, will be included in this prospective randomized study. Patients will be randomly allocated to either of 2 study groups of 35 patients each by computer generated randomization codes contained in sealed, sequentially numbered envelopes.

Clinical Significance Real time ultrasonography might facilitate the performance of the spinal anaesthesia in patients in whom technical difficulties are expected. It might be helpful in patients where traditional landmark technique is not beneficial like patients with difficult topography anatomy of spine.

Keywords: Real time ultrasound, spinal anaesthesia, surface landmark, difficult spine.

(Signature)	(Signature)	(Signature)	(Signature)	(Signature)
Candidate	Co-supervisor	Co-supervisor	Supervisor	Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"COMPARISON OF REAL TIME ULTRASOUND ASSISTED VERSUS CONVENTIONAL LANDMARK TECHNIQUE FOR SPINAL ANAESTHESIA IN PATIENTS WITH DIFFICULT SPINE ANATOMY"** exist in the Department of Anaesthesiology at Dayanand Medical College and Hospital, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate herself under our supervision and guidance.

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Date: 19/3/21

APPROVAL PROFORMA
BY
RESEARCH & ETHICAL COMMITTEE
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA

Name of candidate	Dr Anita
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Date of enrollment	26th July 2020
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Dr. Harpreet Kaur (Professor & Head, Pathology)	Mr. R K Sharma (Legal Expert)
Dr. Jaspal Singh (Professor & Head, Surgery)	Dr. Ramit Mahajan (Associate Professor, Gastroenterology)
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Approved: Yes / No

Dr. Sandeep Puri
Chairperson
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Approved: Yes / ~~No~~

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PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

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3	COURSE OF STUDY AND SUBJECT	MD Anaethesia
4	DATE OF ADMISSION OF COURSE	25th july 2020
5	TITLE OF THE TOPIC	COMPARISON OF REAL TIME ULTRASOUND ASSISTED VERSUS CONVENTIONAL LANDMARK TECHNIQUE FOR SPINAL ANAESTHESIA IN PATIENTS WITH DIFFICULT SPINE ANATOMY

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Subarachnoid block has been conventionally performed using palpation of bony landmarks to identify the level and point of needle insertion.[1] Manual palpation of the subarachnoid space is done using Tuffier line (the horizontal line connecting the superior iliac crests) as a surface landmark, which is a blind technique.[2] However, in patients with poorly palpable surface landmarks and positioning challenges such as lumbar scoliosis, osteoarthritis, kyphoscoliosis and previous spinal surgery, neuraxial blocks can be difficult to perform. The resultant multiple attempts to administer spinal anaesthesia in these individuals increases the risk of post dural puncture headache, paresthesia, spinal hematoma, radicular pain and blood tap in the spinal needle.

According to the second American Society of Regional Anaesthesia Consensus on Neuraxial Anaesthesia and Anticoagulation, the ideal approach to provide spinal anaesthesia is via a single skin puncture with no needle redirection.[3,4]

In this context, neuraxial ultrasound allows anaesthesiologist to preview spinal anatomy, identify paramedian position and determine the intervertebral space for accurate needle placement. Ultrasound can be used as an alternative or an addition to manual palpation method to identify intervertebral space in patients with difficult spinal anatomy. Ultrasonography of the lumbar spine reveals anatomical information that is not obtained by physical examination, including depth of the ligamentum flavum, width of the interspinous spaces, and spinal bone abnormalities, including scoliosis.[5] Pre-procedural ultrasound scanning is especially beneficial in patients whose surface landmarks are difficult to palpate or are distorted due to obesity, spinal abnormalities or previous spinal surgeries.[6] Although pre procedural ultrasound-guided technique has shown higher success rates than landmark-based technique but it also has certain limitations.[5] With pre procedural ultrasound technique there is a potential for error in the process of having to “remember” the degree of cephalad to caudad and lateral to

medial angulation required after pre-puncture skin marking. Also skin distortion in elderly patients with mobile and loose skin might result in an inaccurate needle insertion point. Lastly, there is an inherent degree of inaccuracy when marking the needle insertion point on the skin during the pre procedural scan.[7] A real time ultrasound guided approach might further improve on these limitations of ultrasound-assisted pre-puncture techniques.[8]

There are limited studies which have compared the real time ultrasound guided paramedian approach for spinal anaesthesia with conventional paramedian landmark technique in patients with difficult spine anatomy.[9] So we propose to conduct a study to investigate whether real time ultrasound guided paramedian technique of spinal anaesthesia offers any advantage over conventional landmark paramedian technique in patients with difficult spine anatomy.

We hypothesize that real time ultrasound scanning will facilitate subarachnoid block and improve first attempt success rate in patients with difficult spine anatomy.

6.2 REVIEW OF LITERATURE

The first planned spinal anaesthesia for surgery was administered by August Bier in 1898.[10] Spinal anaesthesia has been traditionally performed using a surface landmark based 'blind' technique .Landmark guided spinal anaesthesia can be performed using midline, paramedian and lumbosacral approaches.[11] It is commonly used in the fields of urological, gynecological, obstetric, lower limb vascular, orthopedic, lower abdominal and perineal surgery. It provides excellent operating conditions for surgery below the umbilicus.[12] Correct identification and cannulation of the subarachnoid space determine the success or failure of the technique. However ,subarachnoid block can be difficult and challenging for the anaesthesiologist in cases where surface landmarks are absent, indistinct and distorted because of obesity, previous spinal surgery, deformity and degenerative changes of ageing.[7] In such cases multiple insertion attempts are associated with several complications like epidural hematoma, nerve damage, post dural puncture headache and infection.[12-17] This may lead to pain, discomfort, dissatisfaction and refusal by the patients to have spinal anaesthesia again.

Bogin and Stulin were first to use ultrasound for lumbar puncture in 1971.[18] Since then ultrasound imaging has become a popular tool to perform neuraxial anaesthesia. Ultrasound is capable of identifying the precise location of an interlaminar space through which a needle can be advanced, thus it helps in facilitating the successful central neuraxial blockade.[19] Pre-procedural ultrasound guided spinal anaesthesia helps to reduce the number of multiple insertion attempts, hence more acceptable and less risky for the patient.[11] Real time ultrasound might offer an additional advantage of taking into account any patient positional changes as well as trajectory guidance during needle insertion.

Chin KJ et al., conducted a prospective, randomized, controlled trial to investigate the impact of an ultrasound- guided technique on the ease of performance of spinal anaesthesia in patients with difficult surface anatomic landmarks. Poor surface anatomic landmarks are highly

predictive of technical difficulty in neuraxial blockade. They showed that the ultrasound assistance improved the efficacy of spinal anaesthesia compared with the surface landmark in their randomized study. They found that successful dural puncture on the first needle insertion attempt was achieved in twice as many patients in ultrasound group than in surface landmark group. However they reported that more time was required to establish landmark via ultrasound guided technique as compared to palpation with surface landmark technique.[7]

Park SK et al., did a prospective, randomized, controlled study on 44 patients and compared the ultrasound guided and landmark guided technique on patients with abnormal spine anatomy. They concluded that the pre-procedural use of ultrasound significantly reduced the technical difficulties of spinal anaesthesia in patients with abnormal spinal anatomy compared with the landmark – guided technique.[20]

Kampitak W et al., conducted prospective, randomized, controlled study on 70 patients comparing landmark technique and ultrasound guided approach in paramedian spinal anaesthesia in patients of age more than 65 years undergoing total knee or hip arthroplasty. They found that the use of pre- procedural ultrasound guidance in paramedian spinal anaesthesia in elderly patients resulted in a significant decrease in the number of needle redirection and insertion attempts as well as reduction in associated complications compared with the conventional paramedian technique.[11] They preferred paramedian approach in elderly patients because of presence of degenerative changes in the structural elements of the spine, narrow interspinous and interlaminar spaces, ossification of ligaments, and hypertrophy of facet joints.

Rizk MS et al., did a prospective, randomized, controlled study on 180 patients for comparing the pre-procedural ultrasound and conventional surface landmark technique for spinal anaesthesia in elderly patients. They concluded that pre-procedural ultrasound scan did not improve the ease of spinal anaesthesia as compared to the conventional landmark technique.[1]

Srinivasan KK et al., did a prospective, randomised, controlled study on 120 elderly patients scheduled for elective lower limb joint arthroplasties and compared pre-procedural ultrasound-guided paramedian vs landmark-guided midline approach for spinal anaesthesia. They concluded that routine use of pre-procedural ultrasound guided spinal anaesthesia in these patients did not reduce the number of passes or attempts needed to achieve successful dural puncture.[21]

Chin KJ et al., did a prospective descriptive study on 50 elderly patients undergoing elective total joint arthroplasty under ultrasound assisted spinal anaesthesia. The results of this study suggested that pre-procedural ultrasound assisted subarachnoid block in older population posted for orthopaedic surgery is both feasible and potentially useful in identifying the lumbar intervertebral spaces and provide an accurate measure of the depth to the intrathecal space. As it was an observational study, they could not conclude the superiority of ultrasound-assisted spinal anaesthesia compared with the surface landmark-guided technique.[19]

Elsharkawy H et al., did a randomized controlled clinical trial on thirty eight patients scheduled for total hip or knee arthroplasty and compared real time ultrasound guided paramedian versus landmark guided spinal anaesthesia in patients meeting criteria for difficult spine anatomy with age fifty five years or more. They concluded that real time ultrasound guided spinal anaesthesia in these patients required longer time with lower needle insertion attempts as compared to control group.[9]

After thorough literature search, we could find only a single study on use of real-time ultasonography for difficult spinal anatomy. Hence, we propose to study and compare the paramedian approach for spinal anaesthesia with real time ultrasound guidance versus landmark technique in our patients with difficult spinal anatomy.

6.3 AIMS AND OBJECTIVES OF THE STUDY

Primary Aim To compare the rate of successful dural puncture between ultrasound assisted paramedian technique versus landmark guided paramedian technique in patients with difficult spine.

Secondary Aim

- To compare the number of needle insertion attempts and needle redirections required for successful dural puncture in both groups.
- To compare the total procedure time.
- To compare peri-procedural pain, discomfort scores and complications if any.

7. MATERIALS AND METHODS

7.1 SOURCE OF DATA

The study will be conducted in the Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after the approval of Institutional Ethics Committee. Seventy patients belonging to American Society of Anaesthesiologists (ASA) grade I-III, aged 18 years or more of either sex with difficult spine anatomy, scheduled for elective surgeries under spinal anaesthesia, will be included in this prospective randomized study.

7.2 METHOD OF COLLECTION OF DATA

Inclusion Criterion:

Patients more than 18 years old presenting for elective surgery under subarachnoid block will be considered eligible for enrolment if they have difficult spine anatomy as assessed by presence of any one of the following:

- Lumbar spine deformity: kyphosis, lordosis or scoliosis
- Poorly palpable or impalpable spinous processes.
- BMI ≥ 30 kg/m^2

Exclusion Criterion:

- Refusal for spinal anaesthesia
- Coagulopathy
- INR > 1.5, platelet count <100 x 10^9/L
- Local site infection
- Allergy to local anaesthetic drugs
- Patients having any contraindications to spinal anaesthesia

Number of Cases

Our sample size came out to be 35 subjects per group.

Group Allocation

A total of 70 eligible patients will be randomly allocated to either of two study groups of 35 patients each by computer generated randomization codes sealed in sequentially numbered envelopes.

- Group A - will receive spinal anaesthesia by conventional surface landmark- guided paramedian technique.

- Group B - will receive spinal anaesthesia by an ultrasound guided paramedian technique

Methodology

PREANAESTHETIC CHECKUP

A thorough history and physical examination will be conducted. Baseline patients characteristics such as; age, gender, BMI, presence of any spinal abnormalities and history of any spinal surgery in past will be recorded. Routine investigations will be done in all patients according to institutional protocol. Patients will be randomly allocated to either of two study groups of 35 patients each by computer generated randomization codes contained in sealed, sequentially numbered envelopes.

Group A: will receive spinal anaesthesia by the conventional surface landmark paramedian technique.

Group B - will receive spinal anaesthesia using real time ultrasound guided paramedian technique.

A written informed consent will be taken from all the patients. After arrival of the patient to operation theatre, standard monitoring will be done (Electrocardiogram, non-invasive blood pressure measurement and oxygen saturation). Intravenous access will be established in all patients. Pre procedure and post procedure vitals will be noted.

ANAESTHESIA TECHNIQUE

Patients will be placed in a sitting position and back will be flexed. Under all aseptic precautions a large area of lumbo-sacral spine will be painted using antiseptic solution. In group A, surface anatomic landmarks will be palpated to determine the location of paramedian lumbar intervertebral space and time taken will be noted as assessment time. Lidocaine 2% will be used for skin infiltration. Spinal anaesthesia will be performed in best palpable space between L2- L5 using standard paramedian approach by an anaesthesiologist with more than 5 years of clinical experience, using a 23 gauge Quinke needle. The time between start of needle insertion and achievement of free flow of CSF will be noted as procedure time.

In group B, with patient in sitting position and full asepsis, ultrasound imaging of the lumbar spine using a SonoSite Edge II Total (SH Serial number 04N1DC) ultrasound machine and a low-frequency (2–5 MHz) curved-array probe will be done. Anaesthesiologist having an experience with more than 30 ultrasound-guided subarachnoid blocks will perform the procedure in all patients. Probe will be applied to the patient's back, in the paramedian plane. The sacrum will be identified first and then the probe will be moved cephalad in the paramedian axis and will be tilted 10–15 degree towards midline. The lumbar lamina and interlaminar spaces between L2-3, L3-4 or L4- L5 will be identified. Probe will be positioned with its midline point directly above intervertebral space. The transducer will be then rotated 45 degrees towards midline, into an oblique, paramedian sagittal view. The quality of scan in parasagittal oblique view will be graded on basis of visualization of ligamentum flavum/duramater complex (LFD) and posterior longitudinal ligament (PLL). It will be graded as good (both LFD and PLL visible), intermediate (either LFD or PLL visible) or poor (both LFD and PLL not visible). The level/space at which quality of scan will be best shall be chosen as target space for needle insertion. The time from placement of probe to identification of best space will be taken as assessment time. Lidocaine 2% will be used for skin infiltration. Quinke needle (23 gauge) will then be inserted in plane from the caudal end of the ultrasound transducer with its tip directed towards the interlaminar space. The needle will be gradually advanced to the interlaminar space, under real-time in-plane ultrasound guidance, until the tip will be judged to have pierced through the ligamentum flavum/dura complex. Stylet will be withdrawn to confirm free flow of CSF. The time between starting of needle insertion and achievement of CSF will be noted as procedure time.

After achieving successful dural puncture as confirmed by free flow of cerebrospinal fluid from the needle hub, intrathecal anaesthetic solution will be injected in both groups. Both the ultrasound guided and surface landmark spinal anaesthesia will be performed by the same anaesthesiologist.

A total of six attempts (needle insertion plus redirection attempts) will be allowed. Needle insertion attempt is defined as number of separate skin punctures made by needle while needle redirection attempt is defined as any change in needle insertion trajectory that does not involve complete withdrawal of needle from the patients skin. The anaesthesiologist will be given the discretion to attempt in a different lumbar intervertebral space if deemed necessary, and this will be noted. If dural puncture is unsuccessful even after six attempts (needle insertion plus redirection attempts), these patients will be treated as failed attempt. The anaesthetist will have the option to use alternate techniques including -a senior anaesthesiologists help, midline approach with landmark or ultrasound guided technique or general anaesthesia.

Outcome:

Primary outcome

- To compare the first needle insertion attempts required for successful acquisition of CSF with both the techniques.

Secondary outcome

- To compare the number of needle insertion attempts and needle redirections required for successful dural puncture in both groups.
- To compare the total procedure time.
- To compare peri-procedural pain, discomfort scores and complications if any.

Group A –

(a)Assessment time: Time taken to identify the best intervertebral space by palpation

(b) Procedure time: Time taken from insertion of needle to acquisition of CSF

(c) Total procedure time (a+b): Sum of assessment time and procedure time.

Group B –

(a) Assessment time: Time taken from first placement of probe on the skin to the anaesthesiologist declaration of best visualization of the view.

(b) Procedure Time: Time taken from insertion of needle to acquisition of CSF

(c) Total procedure time (a+b): Sum of assessment time and procedure time.

Associated pain score and discomfort score

- **Peri-procedural pain-**

After completion of procedure, patient will be asked to rate pain in back during administration of spinal anaesthesia, using 11 point numeric rating scale (0-10)

0 – no pain, 10- worst pain

- **Peri-procedural discomfort score:** 6 point score based on numeric rating scale (0-5)

Discomfort during the overall neuraxial procedure will be rated, including any uncomfortable feeling due to positioning, anxiety, or fear

0 – no discomfort 5 - worst discomfort

Statistical Analysis

Data will be described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups will be done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively. For comparing categorical data, Chi square ($\chi 2$) test will be performed and exact test was used when the expected frequency is less than 5. A probability value (p value)less than 0.05 will be considered statistically significant .All statistical calculations will be done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows

A post hoc power analysis was conducted using the software package, G*Power version 3.1.9.2 (Franz Faul, university kiel, Germany). The alpha level used for this analysis was $p<0.05$ and beta was 0.20. Sample size was estimated from the results of previous study(11) using the first attempt success rate as the parameter, which

is the primary outcome of our study. Our sample size came out to be 35 subjects per group at power of 0.98 and with an effect size of 1.81 with 10% chance of error with $\alpha = 0.05$, $\beta = 0.20$ and confidence interval of 95%.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

No

7.4 HAS ETHICAL CLEARENCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached alongwith.

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PROFORMA

S. No.

Name- Age/gender -

MRD No. - Group -

Height - Weight(in kg)-

ASA Physical status - BMI(kg/m^2) -

Type of surgery - Date of surgery –

H/O previous spinal surgery in the past - ☐ YES ☐ NO

Lumbar spine deformity: ☐ Present ☐ Absent

☐ Kyphosis ☐ Scoliosis ☐ Lordosis

Spinous processes - ☐ Poorly palpable ☐ Impalpable

Routine investigation -

Hemoglobin (gm/dl)	
T.L.C (10^3/ul)	
P.Count (10^3/ul)	
PTI/INR	

Pre procedure vitals Post procedure vitals:

HR=	HR=
BP=	BP =
SPO_2=	SPO_2=
RR=	RR=

Signature of Candidate **Signature of Supervisor**

Assesment time	Procedure time	Total procedure time

Number of needle insertion	Number of needle redirection	Total needle attempts

Space of successful block:

Any change of paraspinal space:

Periprocedural pain score - based on numeric rating scale(0-10)

Score 0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**Score 10**
No pain										**Worst pain**

Periprocedural discomfort score- based numeric rating scale (0-5)

Score 0	**1**	**2**	**3**	**4**	**Score 5**
No discomfort					**Worst discomfort**

Group B : View of ultrasound guided technique –

☐ Good ☐ Intermediate ☐ Poor

Complications – ☐ Paraesthesia ☐ Bloody tap

Failure of technique - ☐ Yes ☐ No

Conversion of technique-

☐ Landmark guided to ultrasound guided technique

☐ Ultrasound guided to landmark guided technique

☐ Converted to general anaesthesia

Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o..... .....am willing to participate in the study **"COMPARISON OF REAL TIME ULTRASOUND ASSISTED VERSUS CONVENTIONAL LANDMARK TECHNIQUE FOR SPINAL ANAESTHESIA IN PATIENTS WITH DIFFICULT SPINE ANATOMY"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests or extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out of the study any time without assigning any reason.

....

Signature of the Witness Signature of the patient

Name:

Signature of Supervisor **Signature of Candidate**

मरीज अनुमति फार्म

तिथि _____

मैं _____पत्नी/पुत्र/पुत्री _____ निवासी _____ इस शोधकार्य **"COMPARISON OF REAL TIME ULTRASOUND ASSISTED VERSUS CONVENTIONAL LANDMARK TECHNIQUE FOR SPINAL ANAESTHESIA IN PATIENTS WITH DIFFICULT SPINE ANATOMY"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____ਵਾਸੀ

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"COMPARISON OF REAL TIME ULTRASOUND ASSISTED VERSUS CONVENTIONAL LANDMARK TECHNIQUE FOR SPINAL ANAESTHESIA IN PATIENTS WITH DIFFICULT SPINE ANATOMY" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

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ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

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ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

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ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ